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VITEK 2™ — technology

Online Software User Manual

BIOMÉRIEUX

bioMérieux, Inc.
Box 15969
Durham, North Carolina 27704-0969 / USA
Tel. (1) 800-682-2666

EC REP

bioMérieux® SA
au capital de 11 879 045 €
673 620 399 RCS LYON
69280 Marcy l'Etoile / France
tél. 33 (0)4 78 87 20 00 / fax 33 (0)4 78 87 20 90
http://www.biomerieux.com

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Argentina
bioMérieux Argentina s.a.
Av. Congreso 1745
(C1428BUE) Capital Federal
Buenos Aires
tel. (54) 11 5555-6800
fax (54) 11 5555-6888

Australia
bioMérieux Australia P/L
Unit 25, Parkview Business Center
1 Maitland Place
Baulkham Hills NSW 2153
tel. (61) 2 8852 4700
fax (61) 2 8852 4777

Austria
bioMérieux Austria GmbH
Eduard-Kittenberger-Gasse 97
Top 3
A-1230 Wien
tel. (43) 186 50 650
fax (43) 186 50 661

Belgium
bioMérieux Benelux s.a./n.v.
Media Square
18–19 Place des Carabiniers
Bruxelles 1030
tel. (32) 2 743 01 70
fax (32) 2 733 55 97

Brazil
bioMérieux Brasil SA
Estrada Do Mapuá
491 Taquara - Jacarepaguá
CEP 22710 261 Rio de Janeiro RJ
tel. (55) 21 2444 1400
fax (55) 21 2455 6099

Canada
bioMérieux Canada, Inc.
7815, Henri-Bourassa West
Saint Laurent, QC
H4S 1P7
tel. (1) 514 336 7321
fax (1) 514 807 0015

Chile
bioMérieux Chile S.A.
Seminario 131
Providencia
Santiago
tel. (56) 2634 20 92
fax (56) 2634 20 93

China
bioMérieux China Limited
17/Floor, Yen Sheng Centre,
64 Hoi Yuen Road,
Kwun Tong
Kowloon - Hong Kong
tel. (852) 2356.7033
fax (852) 2330.2085

Colombia
bioMérieux Colombia Ltda
Avenida 15 No. 100-43
Piso 2
Bogotá D.C.
tel. (57) 1 520 0080
fax (57) 1 520 0088/1 520 0831

Denmark
bioMérieux Danmark Aps
Smedeholm 13C
2730 Herlev
tel. (45) 70 10 84 00
fax (45) 70 10 84 01

Finland
bioMérieux Suomi Oy
Rajatorpantie 41 C
01640 Vantaa
tel. (358) 9 8545 6000
fax (358) 9 8545 6045

France
bioMérieux SA
69280 Marcy l'Etoile
tel. (33) 0(4) 78 87 20 00
fax (33) 0(4) 78 87 20 90
http://www.biomerieux.com

Germany
bioMérieux Deutschland GmbH
Weberstrasse 8
D 72622 Nürtingen
tel. (49) 7022 30070
fax (49) 7022 36110

Greece
bioMérieux Hellas S.A.
Papanikoli 70
15232 Halandri
Athens
tel. (30) 210 81 72 400
fax (30) 210 68 00 880

Hungary
Representation Office
bioMérieux B.V.
Reitter Ferenc u. 39-49
1135 Budapest
tel. (36) 1 412 3880
fax (36) 1 412 3890

India
bioMérieux India Pvt. Ltd
D-45, Defense Colony
New Delhi 110 024
tel. (91) 11 2 464 88 40
fax (91) 11 2 464 88 30

Indonesia
Representation Office
bioMérieux Indonesia
Enseval Building
Kawasan Industri Pulo Gadung -
Jl. Pulo
Lentut No. 10
Jakarta Timur 13920
tel. (62) 21 461 51 11
fax (62) 21 460 41 07

Italy
bioMérieux Italia S.p.A.
Via Fiume Bianco, 56
00144 Roma
tel. (39) 06 52308.1
fax (39) 06 52308.240

Ivory Coast
bioMérieux Afrique Occidentale
08 BP 2634
Abidjan 08
tel. (225) 22 40 93 93/22 40 41 40
fax (225) 22 40 93 94

Japan
bioMérieux Japon, Ltd.
Seizan Bldg.,
12-28 Kita-Aoyama 2-chome
Minato-ku, Tokyo 107-0061
tel. (81) 3 5411 86 91
fax (81) 3 5411 86 90

Korea
bioMérieux Korea Co., Ltd.
7th Floor YooSung Building
830-67, Yoksam-dong,
Kangnam ku
Séoul
tel. (82) 2.547.6262
fax (82) 2.547.6263

Mexico
bioMérieux México SA de CV
Chihuahua 88, col. Progreso
México 01080, D.F.
tel. (52) 55 5481 9550
fax (52) 55 5616 2245

Netherlands (The)
bioMérieux Benelux BV
Boseind 15
P.O. Box 23
5280 AA Boxtel
tel. (31) 411 65 48 88
fax (31) 411 65 48 73

New Zealand
bioMérieux New Zealand Ltd.
22/10 Airbourne Road
North Harbour Auckland
tel. (64) 9 415 0601
fax (64) 9 415 0603

Norway
bioMérieux Norge AS
Økernveien 145
N-0513, Oslo
tel. (47) 23 37 55 50
fax (47) 23 37 55 51

Philippines (The)
Representation Office
bioMérieux Philippines
11th Floor, Pearlbank Centre
146 Valero Street, Salcedo Village
1227 Makati City
tel. (632) 817 7741
fax (632) 812 0896

Poland
bioMérieux Polska Sp. Z.o.o.
ul. Zeromskiego 17
01-882 Warszawa
tel. (48) 22 569 85 00
fax (48) 22 569 85 54

Portugal
bioMérieux Portugal, Lda.
Rua Alto do Montijo, Lotes 1 e 2
Portela de Carnaxide
2794-070 Carnaxide
tel. (351) 21 424 59 80
fax (351) 21 418 32 67

Russia
o.o.o. bioMérieux
Petrovsko-Razoumovskii proyezd, 29
127287 Moscow
tel. (7) 095 212 10 26
(7) 095 424 79 38
fax (7) 095 214 95 41

Spain
bioMérieux España S.A.
Manual Tovar, 45–47
28034 Madrid
tel. (34) 91.358 11 42
fax (34) 91.358 06 29

Sweden
bioMérieux Sverige AB
Hantverksvägen 15
436 33 Askim
tel. (46) 31 68 84 90
fax (46) 31 68 48 48

Switzerland
bioMérieux Suisse s.a.
51, avenue Blanc
Case postale 2150
1211 Genève 2
tel. (41) 22.906 57 60
fax (41) 22.906 57 42

Taiwan
Representation Office
bioMérieux China Limited
Taiwan Branch
RM 608, No. 6-3 Ching Cheng Street
Taipei 105
tel. (886) 2 2545 2250
fax (886) 2 2545 0959

Thailand
bioMérieux Thailand Ltd
Regent House Bldg, 16th Floor
183 Rajdamri Road, Lumpini,
Pathumwan
Bangkok 10330
tel. (66) 2 651 98 00
fax (66) 2 651 98 01

Turkey
bioMérieux Diagnostik A.S.
Değirmen Sok. Nida Plaza Kat:6
34742 Kozyatağı/Istanbul
tel. (90) 216 444 00 83
fax (90) 216 373 16 63

United Kingdom
bioMérieux UK Ltd
Grafton Way, Basingstoke
Hampshire RG22 6HY
tel. (44) 1256.461881
fax (44) 1256.816863

USA
bioMérieux, Inc.
100 Rodolphe Street
Durham NC 27712
tel. (1) 919 620 2000
fax (1) 919 620 2211

Vietnam
Representation Office
bioMérieux Vietnam
17 Nguyen Van Mai, Ward 8
District 3
Ho Chi Minh City
tel. (84) 88 299 599
fax (84) 88 207 898

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PART I: INTRODUCTION AND GETTING STARTED

How to Use This Manual 1

About This Chapter

This chapter gives you important information about the VITEK® 2 Systems software and how to use this manual. bioMérieux recommends that you read this chapter first.

IMPORTANT: ***Read this manual carefully before you attempt to operate the VITEK® 2 Systems software.***

Chapter Contents

Purpose of the VITEK® 2 Systems Software • 1-2
Important Software Features • 1-2
Additional Supplies • 1-2
Purpose of This Manual • 1-3
Intended Audience • 1-3
Manual Organization • 1-3
How This Manual Is Organized • 1-4
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Purpose of the VITEK® 2 Systems Software

Welcome to the System Software for VITEK® 2 products, the *in vitro* diagnostic test software used for identification (ID) and antimicrobial susceptibility testing (AST) of organisms.

The system software is a component used to support the VITEK® 2 instruments. Susceptibility and identification tests performed using the system software are intended for use by clinicians for therapeutic guidance. Additionally, results obtained from identification tests are used for environmental monitoring and quality control purposes in an industry context.

This software user manual describes using the system software to obtain results from the susceptibility tests and identification tests. This manual describes how to use the system software application to perform diagnostic tests using VITEK® 2 instruments. This chapter highlights the new features offered with the workstation software, and describes finding help using this software user manual and other technical resources.

Important Software Features

New features include:

- The VITEK® 2 Systems software runs in a PC environment.
- Easy-to-use system software interface.
- Advanced Expert System™ (AES) for Clinical Use provides therapeutic guidance for advanced analysis of results and the detection of phenotypes.
- Identification for Industry Use allows labs to copy and maintain specific biopattern information for organisms in a Supplemental React File (SRF).
- 21 CFR 11 compliance mode provides the ability to version changes on a laboratory report, archive isolates and audit history to a CD, and prevents deletion of cards.

Additional Supplies

Contact bioMérieux or your local vendor for laboratory supplies and other accessories.

Purpose of This Manual

The user documentation for the VITEK® 2 Systems software consists of this software user manual and the online product information, which are both available in PDF format from the system software Help.

You can easily print this manual from the workstation printer to use as a reference when you are away from the workstation.

Use the online manual to find software-related tasks and product information.

For information pertaining to the instrument or to find out how to perform instrument-related tasks, refer to the VITEK® 2 Compact Instrument User Manual or the VITEK® 2 Instrument User Manual

Note: *Screens and figures are intended for illustrative purposes only and are not to be construed as representations of actual test data, results, or components. Screens and components are not shown to scale.*

Intended Audience

The VITEK® 2 Systems software and this manual are intended for laboratory use by trained, professional, clinical and industrial users.

Most material in this manual applies to both sets of users. If any information in this manual is intended for clinical use only or industrial use only, it is marked *Clinical Use* or *Industrial Use*.

Manual Organization

The following sections explain:

- Manual and Chapter Organization
- Finding Topics and Procedures
- Typographic and Usage Conventions

How This Manual Is Organized

There are four basic parts to this manual:

Part I: Introduction and Getting Started — Introduces the new system and its components and gives quick start information for using this software application.

Part II: Set Up and Manage Test Information — Describes setting up and managing tests, patients, and quality control information.

Part III: View and Maintain Results — Describes viewing, modifying and finalizing isolate results.

Part IV: Configure the Workstation and Maintain System Utilities — Provides instructions for laboratory technologists and supervisors on how to administer the system, generate reports, archive data, and restore the system.

Chapter Organization

All of the workflow and procedural chapters are organized in the same way and include the following:

- *About This Chapter* — Brief description of the chapter's content and, where applicable, an explanation of how to access the menu or menu command that is the subject of the chapter.
- *Chapter Contents* — A table of contents for the chapter
- *Procedures*
- *Background Information*, where applicable and useful

Finding Topics and Procedures

This manual uses several methods to help you find information and keep your bearings:

Table of Contents — Located at the front of this manual. It contains the titles of all chapters/appendices and their sections, and the page number of each title and section.

List of Figures — Located at the front of this manual. It contains a list of all figures in this manual and the page number of each figure.

List of Tables — Located at the front of this manual. It contains a list of all tables in this manual and the page number of each table.

Chapter Contents — Located at the front of each chapter. It lists all sections in the chapter and their page numbers.

Page Headers — Located at the top of each page. There are two parts to a header: the chapter title and the primary section title.

Page Footers — Located at the bottom of each page. There are three parts to a footer: the manual's title, the manual's part number, and the page number.

Index — Located at the back of this manual. It contains topical entries and their page numbers.

Finding Topics Online

The user documentation available with the workstation software is in Adobe® PDF format. When you click the link to open Help, the Software User Manual and the Online Product information open in PDF format.

You can search PDF Files for the specific page number, topic, or term that you need. The Table of Contents appears in the navigation tree to jump from one chapter to the next based on the task you need to perform. The table of contents is one method for finding the topic you need; you can also search for a keyword by using the Adobe Reader® search function or by scrolling to the Index of this book.

This user manual also contains a Glossary with brief descriptions of words that may be unfamiliar. For more detailed help on viewing and searching for topics within a PDF file, refer to Adobe online user documentation.

Typographic and Usage Conventions

Several common typographic conventions are used to distinguish important words displayed on the screen or references to other sections. The following typographic conventions are used throughout this manual.

Genus and Species Names

Family names as well as genus and species names of bacteria are italicized.

Example: *Enterobacteriaceae*

Example: *Clostridium novyi* or *Agrobacterium radiobacter/tumefaciens*

References

References to other sections in this manual are shown in blue. These are hyperlinks within the PDF manual.

Example: See Chapter 13 System Utilities for more information on resetting security settings.

Click

The term “click” refers to moving a mouse pointer to choose or select a command, window, button, icon, or option, then pressing the left, or primary, mouse button to initiate action in the software.

Example: Click **OK.**

Commands

Menu, keyboard, and button commands are in proper case, bold.

Example: **Start > Programs**

Names and Titles

The names and titles of menus, dialog boxes, fields, icons, and toolbar buttons are in proper case, bold.

Example: **Setup** window

The names of windows for views are in proper case, but are not bold.

Example: Configuration view

Press

The term “press” refers to holding down a key on the keyboard to initiate action in the software.

Example: Press **Enter**.

Select

The word “select” is generally used for selecting menus, menu commands, and user navigation.

Example: Select **Main > Configuration > Version**

User Input

Instructions for user input begin with the word “type” or “enter.” These instructions use bold for literal user input and italic for placeholders.

Example of literal user input: log in as **sjones**, and password **sjones**.

In this example, type exactly what you see on the page (sjones in this example).

Example of a placeholder: Enter your *password* before you...

In this example type your assigned password.

Warnings, Cautions, and Information

This manual uses different types of symbols to alert you to important information. Symbols and their associated information are labeled in text where they occur and set off from surrounding paragraphs, as shown in the following examples.

WARNING

Warning is a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of a device.

CAUTION: Caution is a statement that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device, or damage to other property. Where applicable, a caution statement may include a precaution that should be taken to avoid the hazard.

IMPORTANT: ***Important relates to content presented in this manual. It is used to reinforce the importance of your understanding or remembering something.***

Note: *Note supplies additional information about a topic.*

System Cautions/Warnings

The following represent cautions and warnings for the VITEK® 2 Systems and software.

WARNING

Due to the risk of electrical shock, do not open the workstation case or the UPS case.

WARNING

Improper cleaning and maintenance of the workstation PC could increase the risk of biological contamination.

WARNING

Be sure the UPS has adequate ventilation. For details see documentation provided by the manufacturer.

WARNING

Possible hazard associated with bar code reader's laser emission.

CAUTION: Do not change the Desktop Theme and Appearance. Changes to these settings will affect the appearance of VITEK® 2 Systems software.

CAUTION: Ensure adequate ventilation of the workstation PC as specified by the manufacturer.

CAUTION: It is the responsibility of the Laboratory to uniquely identify patient demographic data.

CAUTION: The VITEK® 2 Systems software is intended to provide therapeutic guidance only and should be used in conjunction with clinical indications in making an informed decision.

CAUTION: Follow local regulations when disposing of the workstation components containing batteries, PCBs, or other potentially hazardous waste materials.

CAUTION: Follow the manufacturer's instructions for proper cleaning and maintenance of the Uninterruptible Power Supply (UPS) provided by the manufacturer.

CAUTION: Place the UPS near the floor in a location where it is unlikely to be bumped and/or fall.

Table of Symbols

Symbols that may appear in the instructions for use or on the instrument, package inserts, or packaging include:

CE-Marking of Conformity

Consult Instructions for Use

Use By

Manufacturer

Date of Manufacture

Contains Sufficient for <n> Tests

Keep Dry

Fragile, Handle with Care

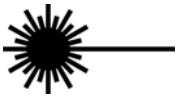
Caution, Consult Accompanying Documents

Biological Risks

Electric Shock Warning

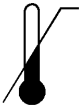
Radiation Warning

Potential Pinch Point Warning



Laser

Temperature Limitation



Upper Limit of Temperature

Lower Limit of Temperature

In Vitro Diagnostic Medical Device

Batch Code

Authorized Representative in the European Community

Catalog Number

Serial Number

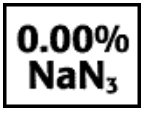
Do Not Reuse

Recyclable

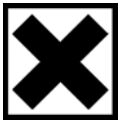
Separate Collection for Waste Electrical and Electronic Equipment

Very Toxic

Corrosive



Sodium Azide



Irritant

Positive Control

Negative Control

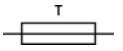
Keep Away From Sunlight

Protect From Light

This Way Up

Do Not Stack

Humidity Limitation



Fuse

Direct Current

Alternating Current

Both Direct and Alternating Current

Three-Phase Alternating Current

Earth (Ground) Terminal

Protective Conductor Terminal

Frame or Chassis Terminal

Equipotentiality

ON (Supply)

OFF (Supply)

ON (Only for a Component of the System Equipment)

OFF (Only for a Component of the System Equipment)

Equipment Protected Throughout by Double Insulation or Reinforced Insulation (Equivalent to Class II of IEC 536)

GETTING STARTED 2

About This Chapter

This chapter provides a system software overview and basic introduction to the navigation. This chapter also provides procedures for accessing and logging in to the system software.

Chapter Contents

System Software Navigation Introduction • 2-2

Basic Navigation • 2-2

Working in the Software Views • 2-3

Main View • 2-3

Main Navigation Areas of the System Software • 2-3

Accessing the System Software • 2-6

Starting the System Software • 2-6

Logging In • 2-8

Logging Out or Quitting the Application • 2-9

Changing Users • 2-10

Managing the Inactivity Timer • 2-10

Customize the Inactivity Timer • 2-10

System Software Navigation Introduction

Basic Navigation

The easy-to-use system software allows for simple navigation to important information. The following define the basic navigation used throughout most of the system software:

1 — Title Bar

2 — Navigation Bar

3 — Left View Bar

4 — Navigation Tree

5 — Action Bar

6 — Right View Bar

7 — Workspace Area

8 — Status Bar

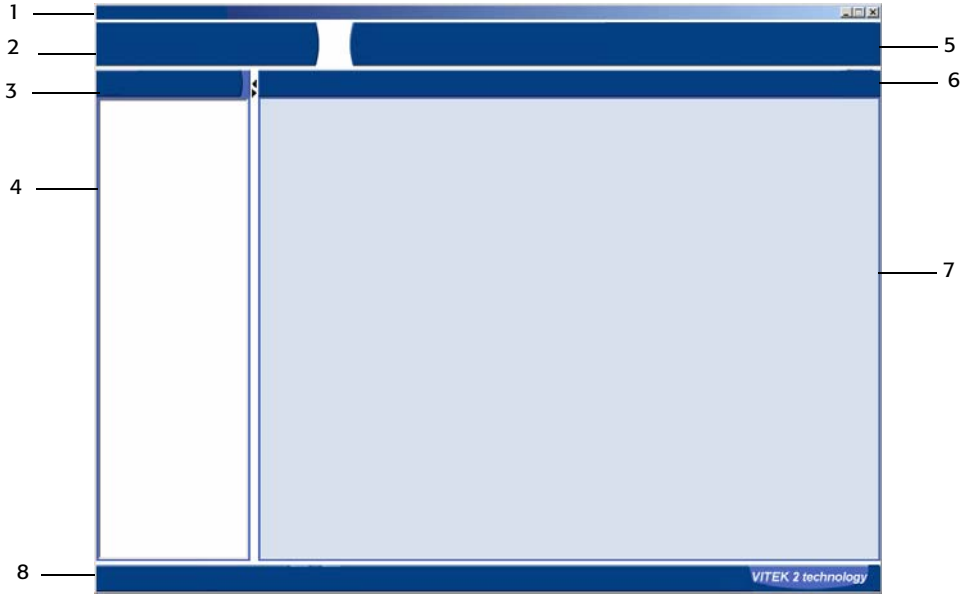


Figure 2-1: Sample View

Working in the Software Views

Much like a Web application, you can navigate from one view to the next from any view within the application, with the exception of the system administration views.

Main View

From the Main view, you can access all of the views that are accessible from the Navigation Bar. You can also access views that help you administer the system (such as the Configuration and System Utilities views). The Main view is a common place for accessing all of the main functional areas within the system software.

Figure 2-2: Main View

Main Navigation Areas of the System Software

The main functional areas within the system software include:

- Manage Cassettes/Set Up Tests Post Entry

- View and Maintain Isolate Results
- Manage Patient Information (Clinical Use)
- Maintain SRF Data (Industrial Use)
- Manage Quality Control (QC)
- Configuration
- System Utilities

TABLE 2-1: MAIN NAVIGATIONAL AREAS OF THE SYSTEM SOFTWARE

View/Icon	Description	Location
Manage Cassettes/Set Up Tests Post Entry	This view allows you to set up tests. You can use this view to set up tests by entering information for virtual cassettes, Smart Carrier Station Cassettes and actual cassettes, as well as quality control tests.	For details, see. Chapter 4 Set Up Test Cards and Cassette Information.
View and Maintain Isolate Results	This view allows you to view and manage test results. You can view isolate summary information, detailed AST information, detailed Biochemical information, and AES summary information. Result reports can be generated and printed from this view. You can also review, approve, and sign results.	For details, see Chapter 8 View and Maintain Isolate Results.
Manage Patient Information (Clinical Use)	The system software allows you to manage and enter patient and specimen information.	For details, see Chapter 5 Manage Patient Information (Clinical Use).

TABLE 2-1: MAIN NAVIGATIONAL AREAS OF THE SYSTEM SOFTWARE

View/Icon	Description	Location
Maintain SRF Data (Industrial Use)	The system software interprets organism identification from biochemical test results using a set of claimed organisms/reactions. For situations where the organism identification is unclear, you will be able to maintain a supplemental react file (SRF).	For details, see Chapter 6 Maintain Supplemental React File (Industrial Use).
Manage Quality Control (QC)	This view allows you to view QC isolate summary information, view QC AST details, view ID details, record lot shipments and review and approve quality control results.	For details, see Chapter 7 Maintain Customer Quality Control.
Configuration	The Configuration views allow you to view configuration parameters. Supervisors can unlock and modify the configuration parameters.	For details, see Chapter 10 Configure and Maintain Workstation.
System Utilities	System Utilities views allow you to create new AST card definitions, search audit history, archive and view archived isolate reports.	For details, see Chapter 13 System Utilities.

Note: *Back up and restore data are external to the system software, for details see Chapter 14 Data Backup and Daily Maintenance.*

Accessing the System Software

After you become familiar with the navigation elements of the system software, the next step involves accessing the application and navigating through each view. The following sections describe accessing the system software:

- Starting the System Software
- Logging In
- Logging Out or Quitting the System Software
- Changing Users
- Manage Inactivity Timer

Starting the System Software

If your workstation computer is turned on and the system software has already been installed, follow these steps to start the application:

1) From the **Start** menu, select **Programs > VITEK 2 Technology > VITEK 2 Systems software** to start the application, or double-click on the VITEK® 2 Technology icon on the desktop.

Note: *Only one session of the system software can run at a time.*

2) A splash screen appears when the system software initializes.

Note: *If the software has recently been restarted, it may take several seconds for the VITEK® 2 Systems software application to start while it is performing normal database startup operations.*

Figure 2-3: Splash Screen

Note: *If an error occurs, a message appears describing the error and providing a suggested course of action. If the system software is already initialized the splash screen will not appear.*

3) Log in to the system software to begin. See Logging In on Page 2-8 for details on logging in to the system.

4) When the application starts up, the inactivity timer initializes. You can customize the inactivity timer. See Customize the Inactivity Timer on Page 2-10 for details.

Logging In

When the login window appears, follow these steps:

1) Type your *User ID* and press **Tab** to proceed to the next field.

2) Type your *Password* and click **OK** or press **Enter**.

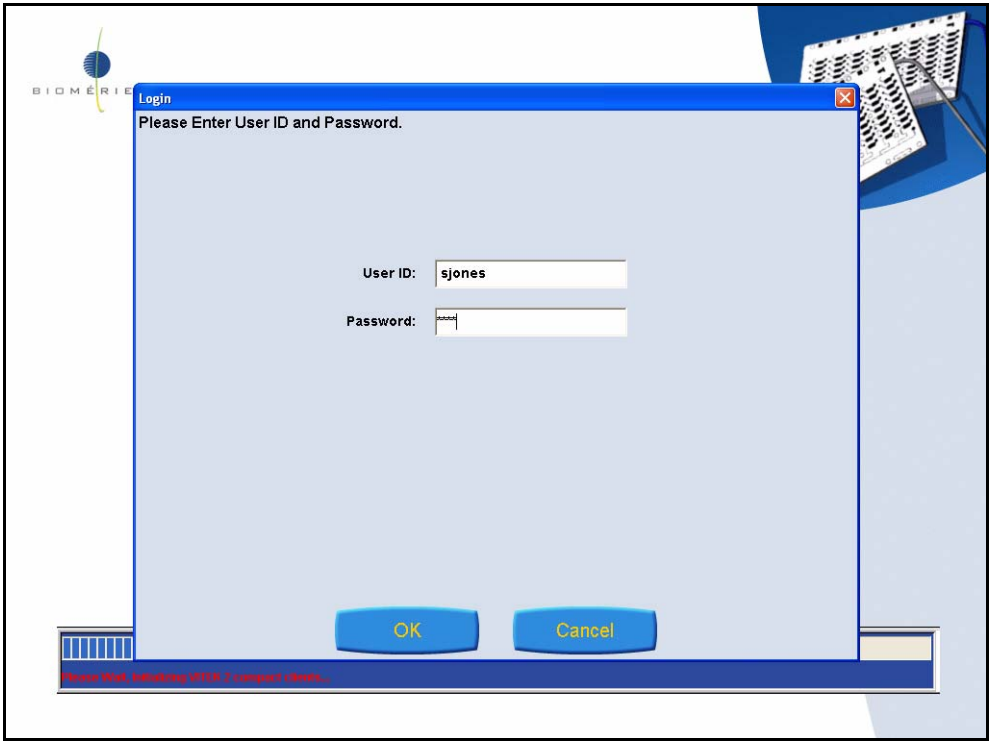


Figure 2-4: Login Screen

3) If you are an authorized user, the system software opens and you can begin working in the application.

If you are unable to access the application due to an invalid User ID and Password, a message appears.

After several attempts, if you still cannot access the application, your user account will be locked.

Note: *(Supervisor Only) As a supervisor, you retain more extensive rights regarding maintaining user accounts. When logging in to the system software, you may be prompted to clear locked User IDs.*

Logging Out or Quitting the Application

There are two methods for logging out of the system software. You can choose to quit the application or you can click the **Login** icon or click the X in the upper right corner of the screen. Logout ends the current session, and you cannot continue using the application until you have logged in again. While Logout keeps the application open and running, quitting the application automatically logs the user out and closes the application session and window. To regain access to the system software, you must start the application again, and log in.

To log out or quit the application:

1) Click the **Login** icon.

Figure 2-5: Login icon

2) The **Logout** window appears.

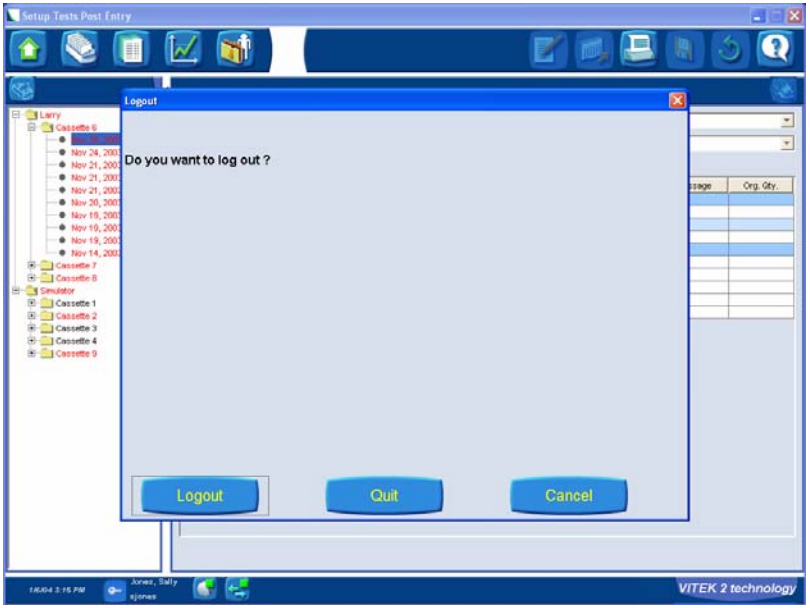


Figure 2-6: Logout window

3) There are several methods for logging out.

- If you want to log out without quitting the application, click **Logout.**
- If you want to log out and Quit the application, click **Quit**.
- If you decide not to log out, click **Cancel** to return to your session.

Changing Users

Changing the user while the application is running consists of logging out without quitting the application. The current user must log out before the new user can log in. For details, see Logging In on Page 2-8 or Logging Out or Quitting the Application on Page 2-9.

When the new user logs in to the workstation, the system displays any warning or error messages generated since the last time the application was initialized.

When the new user logs in, the workstation displays the work area based on the current state of the cassettes.

Managing the Inactivity Timer

If you are logged on to the system software and you exceed the Inactivity time limit, the application will automatically ask you to log in again when you attempt to use the application.

Note: *Any unsaved data will not be recovered when the inactivity time limit has been exceeded.*

Customize the Inactivity Timer

Note: *Only a Supervisor can modify the inactivity timer configuration setting.*

You can customize the inactivity timer as needed. For more details on customizing the inactivity timer settings, see Chapter 10 Customizing the Inactivity Timer.

For details on customizing the general features, see Chapter 10 Customizing General Configuration (Supervisor Only).

Instrument And System Status 3

About This Chapter

This chapter describes how to view, preview, and print information about the instrument status and alarms that pertain to the system software.

Chapter Contents

View and Maintain Instrument Status • 3-2
Instrument Alarm Status Icons • 3-3
View and Print Current Instrument Status • 3-3
View Instrument Monthly Status • 3-4
View and Acknowledge Detected Alarms • 3-6
View Alarm History • 3-7

View and Maintain Instrument Status

Whether there is an alarm condition or not, you can click the **Instrument Status** icon to see the current status of the Instrument. You can also find the monthly history of the status and alarms by clicking on the **Instrument Status** icon located at the bottom of each view.

Note: *If there is more than one instrument connected to the workstation, the software displays a list of available instruments. Select an instrument from the drop-down list to view instrument-specific status information.*

The following instrument status can be checked:

- Current Instrument Status
- Monthly Instrument Status
- View and Acknowledge Detected Alarms (Current Alarms)
- Alarm History

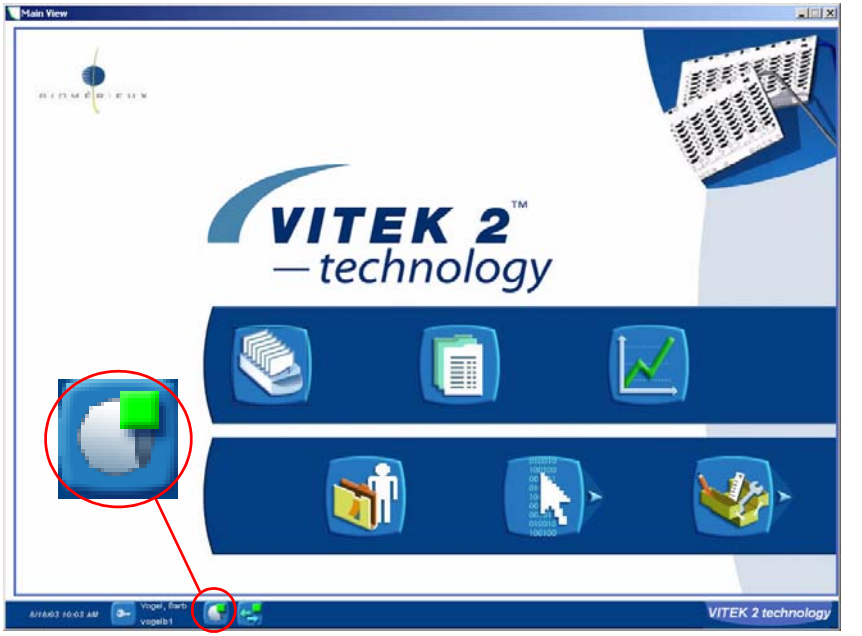


Figure 3-1: Instrument Status Icon

Instrument Alarm Status Icons

OK – The icon with the green square means the connection with the VITEK® 2 instrument is okay. Click this icon to see the instrument status.

Figure 3-2: Instrument OK Status

Warning – The icon with the orange triangle indicates a problem with the instrument. Click this icon to see a description of the warning.

Figure 3-3: Instrument Warning Status

Error – The icon with the red circle indicates an error in the instrument. Click this icon to see a description of the error condition.

Figure 3-4: Instrument Error Status

View and Print Current Instrument Status

You can see instrument parameters by checking the instrument status.

To view Current Instrument Status:

1) Click the **Instrument Status** icon, at the bottom of the screen.

2) Select the Current Instrument Status tab to view the details of the instrument status.

3) The Alarm Messages/Instrument Status window appears.

Note: *If more than one instrument is connected to the workstation, select an instrument from the drop-down list to view instrument-specific status information.*

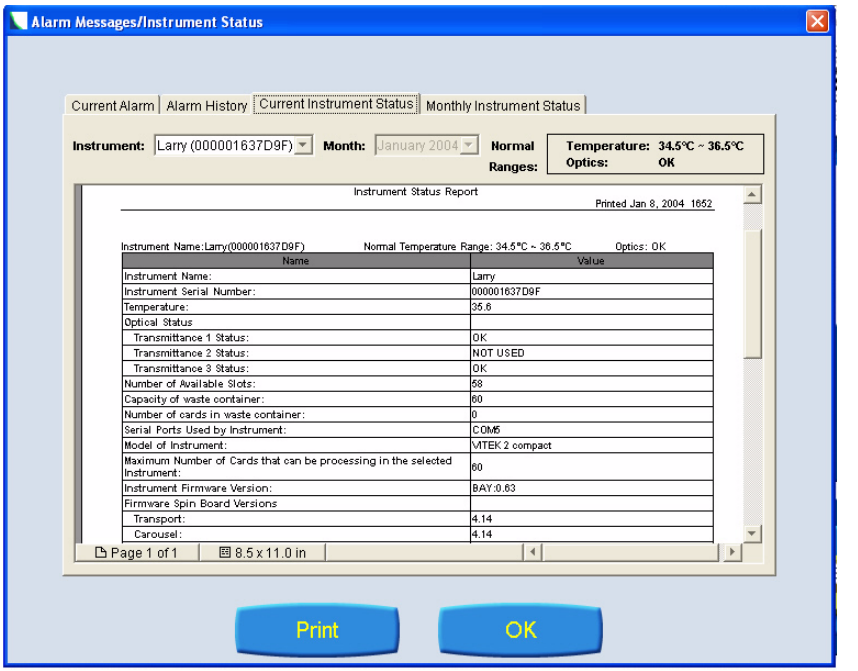


Figure 3-5: Current Instrument Status

To print Current Instrument Status:

4) Click **Print** to print an instrument report with the information that appears in this window. A print window appears.

5) Make the appropriate print selections and click **OK**.

6) The Instrument Status report prints to the workstation printer.

Note: *If more than one instrument is connected to the workstation, select an instrument from the drop-down list to print instrument-specific status information.*

View Instrument Monthly Status

To view a cumulative history of the selected instrument parameters, you can view the monthly status.

Note: *The system software stores temperature and optic readings for four months (the current month plus three previous months). When the status readings surpass four months, they are automatically removed from the system software.*

To view the monthly status:

1) From any view, click the **Instrument Status** icon at the bottom of the screen.

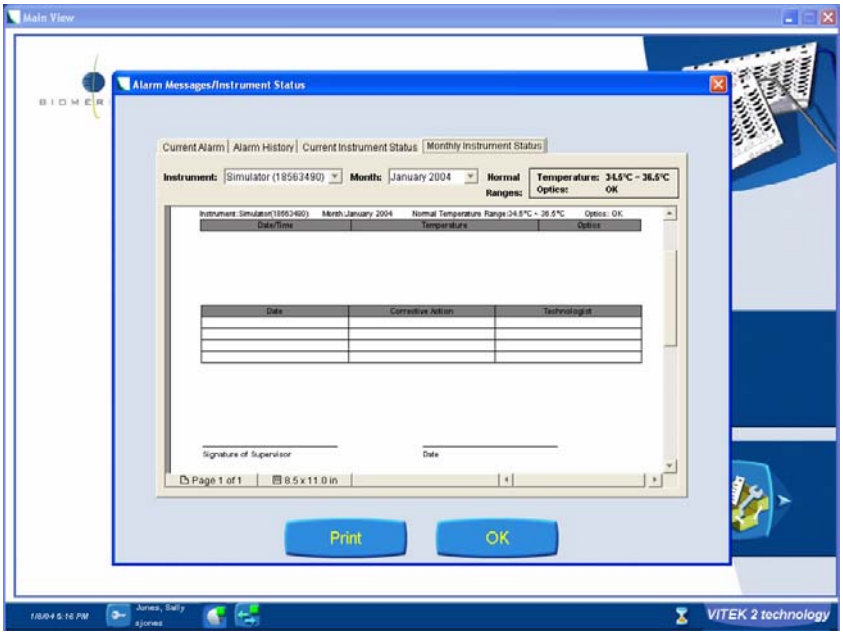


Figure 3-6: Monthly Instrument Status

2) Select the Monthly Instrument Status tab.

3) If there are multiple instrument connections, select the instrument that you want to view from the drop-down list.

4) Select a month to view the status of the instrument from the drop-down list.

5) The system software displays the following information for the instrument for the selected month:

- Normal temperature range and optic status
- Date and time readings taken
- Temperature
- Optic Status

6) You can print an instrument report which includes the information that appears in this window by clicking on the **Print** button.

7) A print window appears. Make the appropriate print selections and click **OK**.

8) The Instrument status report prints to the workstation printer.

View and Acknowledge Detected Alarms

To view all unacknowledged alarms and acknowledge them, follow these steps:

1) You can check the instrument status from any Workspace View.

2) When an alarm is detected, click the **Instrument Status** icon to check the current alarm status.

Note: *Instrument messages are acknowledged at the instrument. The system software only manages system software alarms.*

3) The Alarm workspace appears, and the audible alarm stops sounding.

4) To acknowledge the alarm, click the check box **Acknowledge All Messages.**

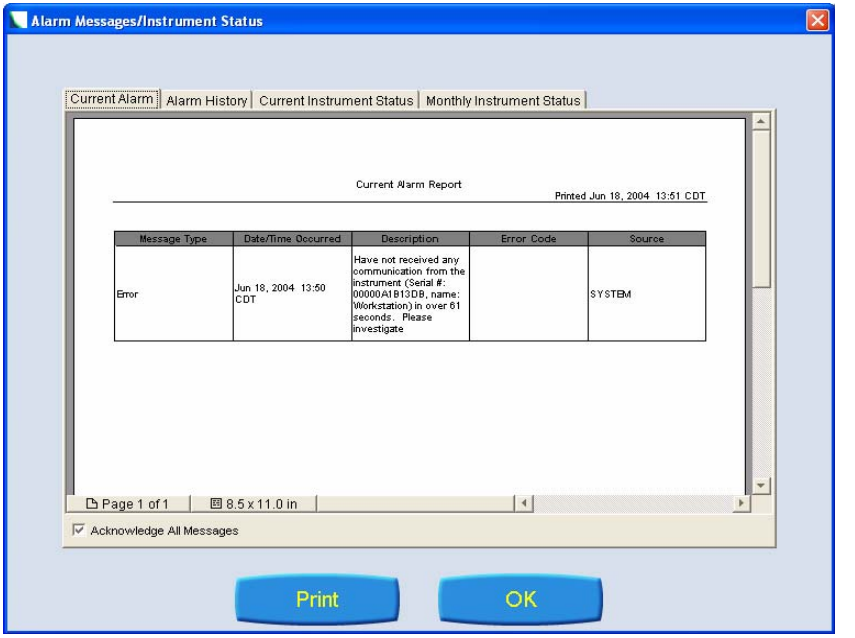


Figure 3-7: Current Alarms

5) Click **Print** to print an alarm report with the information that appears in this window. A print window appears.

6) Make the appropriate print selections and click **OK**.

7) The Instrument status report prints to the workstation printer.

8) Click **OK**.

View Alarm History

The system stores the alarm message history for 30 days before automatically removing it from the system. To view the alarm message history click the **Instrument Status** icon at the bottom of the screen.

To view the alarm message history, follow these steps:

1) From any workspace area, click the **Instrument Status** icon at the bottom of each screen.

2) Click on the Alarm History tab to view the alarm history.

3) The following information appears:

- Type of message
- Date and time the error occurred
- Description including Serial Number and Instrument Name
- Error Code
- Source of the error
- Acknowledge User ID
- Acknowledge Date & Time

Note: *This window displays the instrument and system software alarm history. The alarm history is self-maintaining. Alarms are available for viewing and printing for 30 days after the alarm was logged by the workstation.*

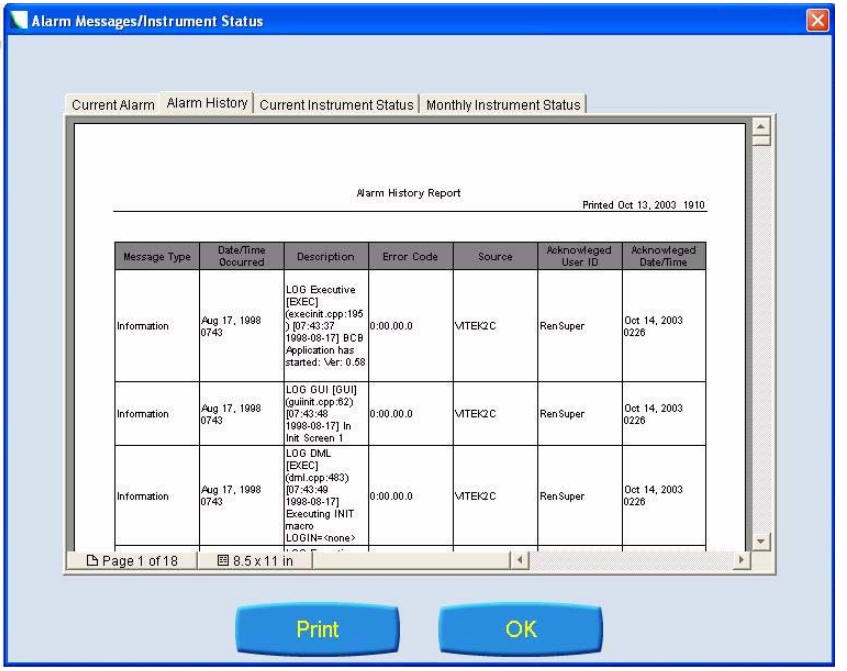


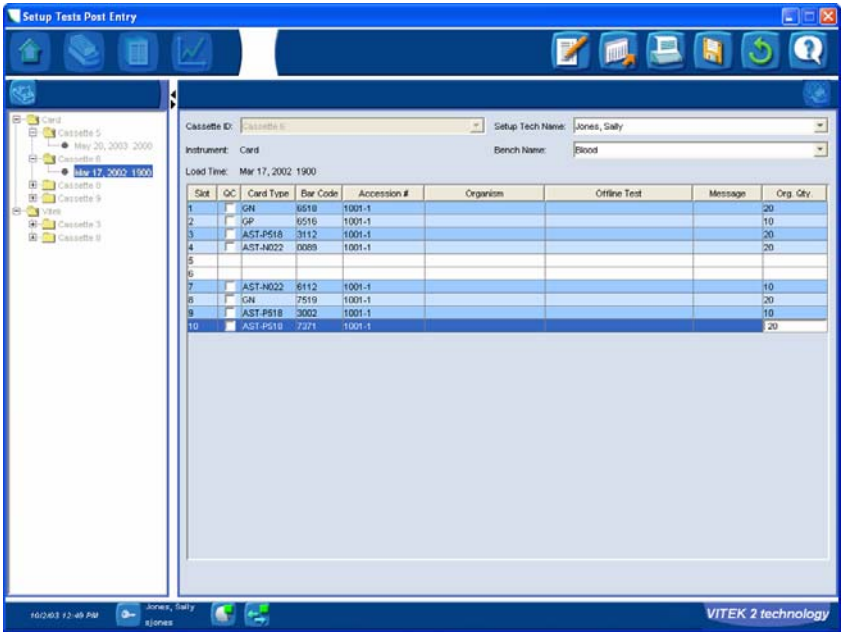
Figure 3-8: Alarm History

4) Click **Print** to print an instrument report with the information that appears in this window. A Print window appears.

5) Make the appropriate print selections and click **OK**.

6) The Instrument Status report prints to the workstation printer.

Part II: Set Up and Manage Test Information


Setup Tests Post Entry
Cassette ID:
Setup Tech Name: Jones, Sally
Instrument: Card
Bench Name: Blood
Load Time: Mar 17, 2002 1900
Slot | QC | Card Type | Bar Code | Accession # | Organism | Offline Test | Message | Org. Qty.
1 GN 6518 1001-1 20
2 GP 6516 1001-1 10
3 AST-P518 3112 1001-1 20
4 AST-N022 6088 1001-1 20
7 AST-N022 6112 1001-1 10
8 GN 7519 1001-1 20
9 AST-P518 3002 1001-1 10
10 AST-P518 7371 1001-1 20
Jones, Sally
sjones
VITEK 2 technology

Set Up Test Cards and Cassette Information 4

About This Chapter

This chapter provides instructions for setting up and maintaining test card, isolate, and cassette information. This chapter also covers entering Quality Control (QC) information.

Note: *If your system software is not yet configured, see* Chapter 10 Configure and Maintain Workstation.

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VITEK® 2 Systems Workflow

There are three methods for setting up test cards:

- **Set Up Tests Post Entry Workflow** – Allows you to load the cassettes first and enter the cassette information after the VITEK® 2 Compact instrument reads the bar codes.
- **Virtual Cassette Entry –** Allows you to create a virtual representation of the cassette information, then load the actual cassettes into a VITEK® 2 Compact instrument.
- **Smart Carrier Station (SCS) –** Allows you to setup a cassette on a dedicated workstation and transfer the saved cassette information to a VITEK® 2 instrument and then on to the VITEK® 2 Systems software.

Note: *When you load the cassette into the instrument, the instrument reads the bar code information from the cards and cassettes and automatically sends the information to the system software. For details on loading the cards and cassettes into the instrument, see the corresponding Instrument User Manual.*

Using the Set Up Tests Post Entry Workflow

When the cassettes have been loaded into the instrument and the cards have been scanned, the cassette appears on the Set Up Tests Post Entry view.

Note: *If 21 CFR 11 is enabled (VITEK 2 Compact), you must be logged on to the system to process cassettes in the Set Up Tests Post Entry workflow.*

To access the Set Up Test Post Entry view:

1) From the Main view, click the **Enter Manage Cassettes view** icon.

Figure 4-1: Enter Manage Cassettes View

2) The Set Up Tests Post Entry view appears.

Note: *While processing cards, when you log in to the system software, the Set Up Tests Post Entry view usually appears displaying a list of cassettes currently loaded in the selected instrument.*

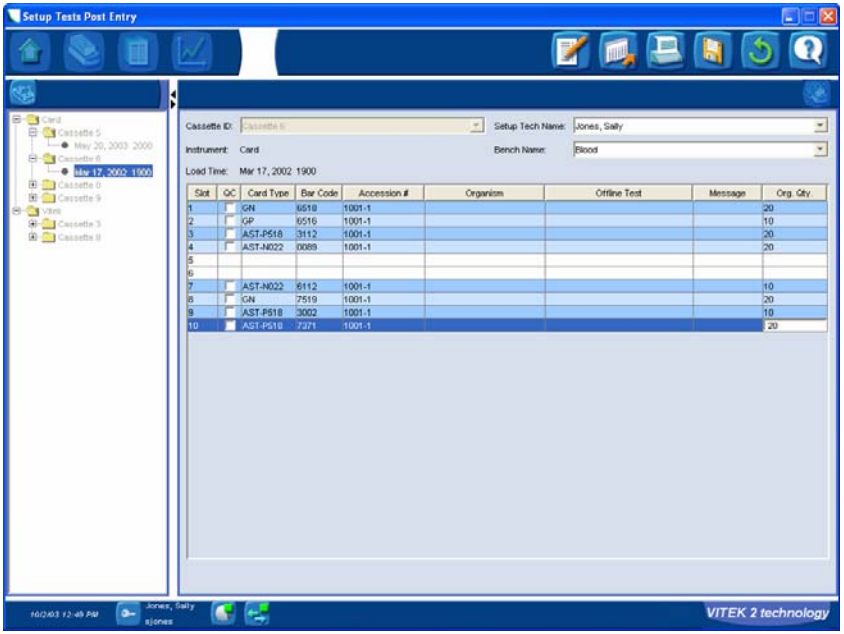

Figure 4-2: Set Up Tests Post Entry View

Cassettes appear in the navigation tree. When a cassette is selected, the following cassette specific information appears in the cassette workspace:

- Dilution Mode (automatic, pre-diluted, automatic and pre-diluted)
- Cassette ID
- Instrument Name
- Load Time and Date
- Setup Technologist's Name
- Bench Name (if enabled in configuration)

Note: *If the instrument name is unknown (i.e., blank), the system software will display* ***???*** *in the instrument name field.*

Note: *A cassette appears in red in the navigation tree when additional information is needed to completely define the selected cassette.*

For details, see Defining the Selected Cassette on page 4-6.

Filtering Cassettes

The Filter option allows you to view and filter the cassettes that appear in the navigation tree.

To filter cassettes from the Set Up Tests Post Entry view:

1) From the first drop-down list that appears in the navigation tree, select whether you want to filter by **Incomplete** cassettes (default filter) or by the **Show All** option.

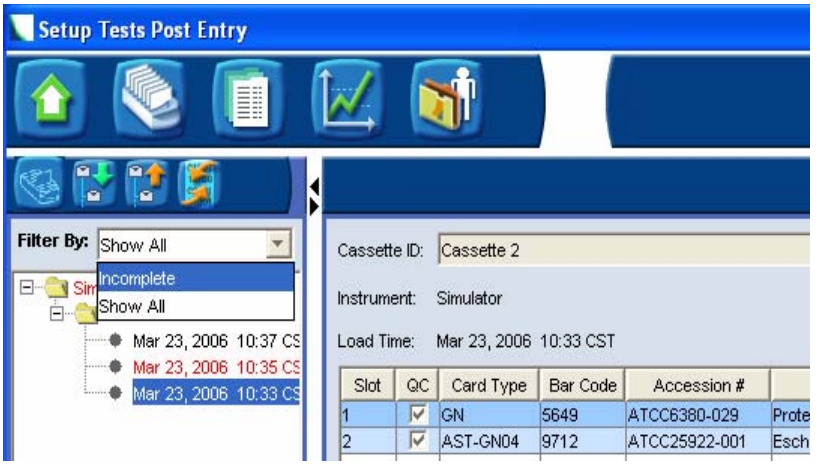

Figure 4-3: Setup Tests Post Entry Filter Options

- **Incomplete** (default) — Workstation only displays incomplete cassettes from the active workspace. Incomplete cassettes appear in red in the navigation tree and require additional information to completely define the selected cassette.
- **Show All** — Workstation displays all cassettes in the active workspace.

Printing a Blank Cassette Worksheet

Before you load a cassette into a VITEK® 2 or VITEK® 2 Compact instrument, you can print a **Blank Cassette Worksheet** and fill in the appropriate information for the cassette.

1) From within the Set Up Tests Post Entry view, click **Print**.

2) The Print Cassette Report window appears.

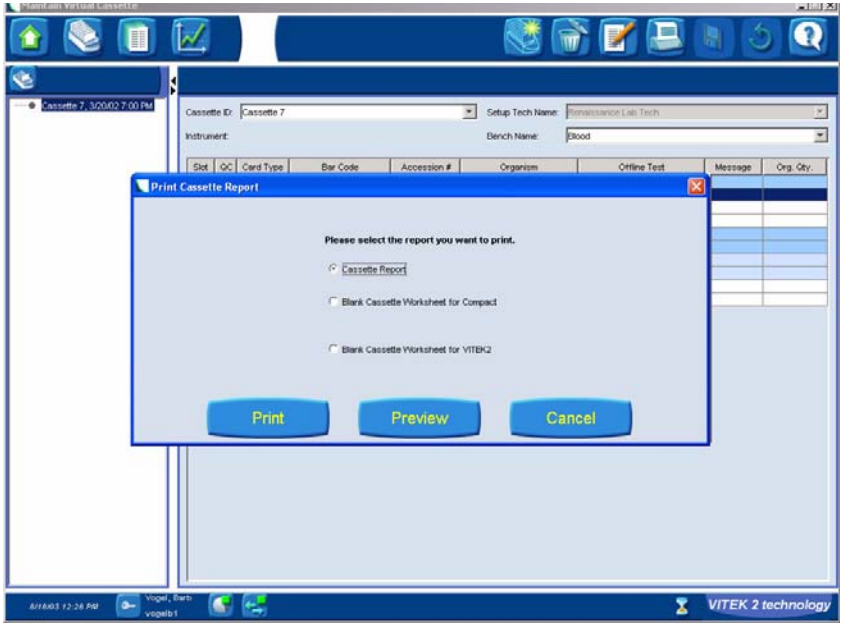

Figure 4-4: Print Cassette Report View

3) Select a **Blank Cassette Worksheet**.

- Blank Cassette Worksheet for Compact
- Blank Cassette Worksheet for VITEK® 2

4) Click **Preview** to see a read-only copy of the blank cassette worksheet.

5) Click **Print** or **Preview** to print or view a copy of the blank cassette worksheet.

6) Use this worksheet to fill in the specific cassette and card information prior to loading the cassette into the instrument.

Preparing Test Cards and Cassettes

Before loading the test cards, you must prepare the test cards. For details on preparing test cards for insertion into the instrument, see the VITEK® 2 Systems Product Information for the particular card type.

Viewing Cassette Information

When you are in the Set Up Tests Post Entry view you can view the cassettes and their status. Any cassettes that need more information to complete

analysis will appear with a **Needs Info** status. The following text representations and definitions will help you understand the cassette status.

Note: *Loaded Cassettes, Virtual Cassettes and Smart Carrier Station Cassettes with incomplete information are displayed in red.*

Table 4-1: Cassette Status Descriptions

Color	Description
Red Text	Needs Info: Cassette needs more information to process the test cards.
Black Text	Cassettes that are complete and ready to process test cards.

A cassette that needs more information to completely process the tests cards may be unable to process for the following reasons:

- Accession Number not defined

Virtual Cassette Reconciliation Problems include:

- Missing card
- Extra card
- Wrong Card

The messages are listed under the **Messages** column in the **Set Up Tests** workspace area.

Defining the Selected Cassette

To select a specific cassette:

1) From the Set Up Tests Post Entry view, select a cassette from the navigation tree.

The cassette you selected appears in the cassette workspace.

2) When you select a cassette, the following information appears in the cassette workspace:

- **Cassette ID** displays the number on the cassette.
- **Name of the Instrument** where the cassette was loaded appears in the cassette workspace.
- **Load Time** displays the date and time the cassette bar code was read by the Instrument.

- **List of Setup Technologists** — select your name from the drop-down list if your name does not already appear in the field.

Note: *If 21CFR 11 Compliance Mode is enabled, you are not permitted to change the Setup Lab Tech Name. When 21 CFR 11 Compliance Mode is enabled, the Setup Technologist is the user logged into the system software when the cassette was loaded in to the instrument.*

- **List of Bench Names (if enabled in configuration)** — select the appropriate bench name or if the Bench name that you are working at does not appear or is incorrect.
- The individual card information for each slot in the cassette appears in a table below the cassette definition information.

3) Enter additional information to further define the individual cards in the cassette. For details on defining individual test cards, see Defining the Cards in the Cassette on page 4-7 in the following section.

Defining the Cards in the Cassette

The cassette workspace also displays the detailed card information in a table that defines each card in the cassette.

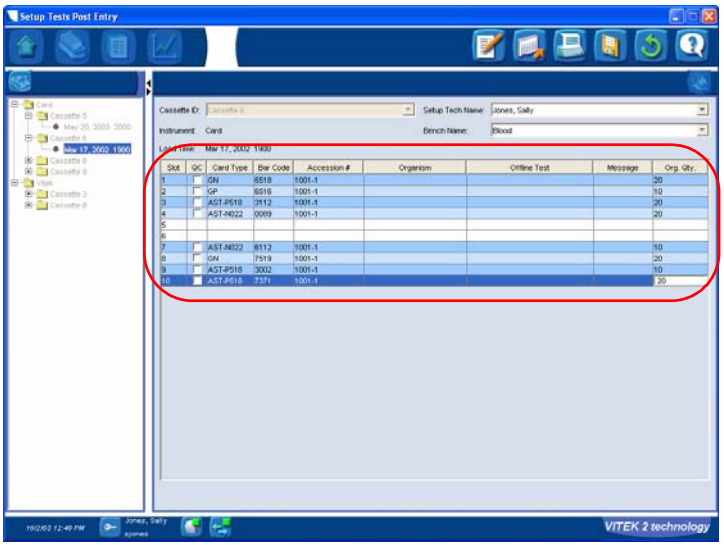

Figure 4-5: Card Definition

The following columns define the cards in the selected cassette:

- Slot

- QC (Quality Control Card)
- Card Type
- Bar code
- Accession # (Laboratory ID number plus the Isolate number)
- Organism
- Offline Test
- Message (Instrument Message)
- Org Qty (Organism Quantity)

Entering Cassette Worksheet Information

When the cassettes are loaded into the instrument, the instrument scans the card bar codes providing an automated method for entering most of the test setup information into the system software.

However, you still need to enter information from the **Blank Cassette Worksheet** to completely process the cards.

1) Select a newly loaded *cassette* from the displayed list in the navigation tree.

The cassette appears in the cassette workspace.

2) Each cassette contains card information for the cards in each slot.

3) Ten slots appear, numbering each card in the cassette. This column is read-only.

4) The card type that was scanned by the instrument appears in the **Card Type** column. This column is read-only.

5) The last four digits of the card bar code appear in the bar code column. This column is read-only.

6) Enter the **Accession #** *or* **Accession ID** (Laboratory Identification Number plus the Isolate Number).

Note: *To enter the Accession ID select the Accession ID cell, and then type in the Lab ID number and the Isolate number. For details on creating isolate groups, see* *Defining Isolate Group Information on page 4-10**.*

7) Select the **Organism Name.** For an AST card, select the Organism name from a drop-down list by selecting the table cell where you need to enter or select the organism name.

8) The status of the card as recorded by the instrument appears in the Message column. This column is read-only.

9) Enter the **Organism Quantity** in the appropriate column.

Select the table cell where you want to enter the organism quantity and type in a quantity based on your laboratory procedures.

Note: *If the cassette defined has already been entered into the system software, then this cassette appears in read-only mode on the screen. The system software also displays the name of the Bench or Setup Tech who entered the information for this cassette.*

The following table defines the card definition columns that appear in the cassette workspace area.

Table 4-2: Card Definition Columns

Card Column	Description	Default Value
Slot	Lists the cards enumerated based on their location within the cassette.	1–10 (VITEK® 2 Compact instrument) 1–15 (VITEK® 2 instrument)
QC	Sets the card up as a Quality Control card. For details see Setting Up and Entering Quality Control (QC) Information on page 4-24.	Not checked
Card Type	Displays the card using the abbreviated card type name.	Card type of card scanned
Bar Code	Displays the last four digits of the card bar code.	Bar code of card scanned
Accession #	The Laboratory Identification number plus the Isolate Number. For details see Defining Isolate Group Information on page 4-10.	Blank
Organism	The organism name from a drop-down list for AST cards.	Blank
Offline Tests	The Offline test can be selected from a drop-down list for AST Cards when the Offline test is required.	Blank
Message	Displays the status message for the card. If the card is loaded and scanned with the appropriate information the value that appears in this column will be **Loaded**.	Loaded

Table 4-2: Card Definition Columns

Card Column	Description	Default Value
Org Qty	The organism quantity. This is a free text field used to record the amount of organism found on the primary isolation plate. For example, 3 +, Heavy.	Blank

Defining Isolate Group Information

To associate test cards you can create isolate groups. An isolate group consists of one or more cards with the same Laboratory Identification Number and Isolate Number.

The isolate number is a number assigned by the lab tech to identify an organism on a culture plate. An isolate number differentiates isolates taken from the same culture. The isolate number values range from 1 to 99.

After the test cards have been scanned, set up the tests by defining isolate information. An isolate group typically consists of an ID card linked to one or more AST cards of the same type.

To define isolate groups and link test cards:

1) From the Set Up Tests Post Entry view, select the cassette that you want to define from the navigation tree.

2) To link an ID card and one or more AST cards, select one identification card and one or more susceptibility cards of the same card class.

Note: *To select multiple cards, click and drag the cursor across the card rows that you want to link to create an isolate group.*

3) Click **Define Isolate**.

Figure 4-6: Define Isolate Icon

4) A window appears allowing you to define the isolate group.

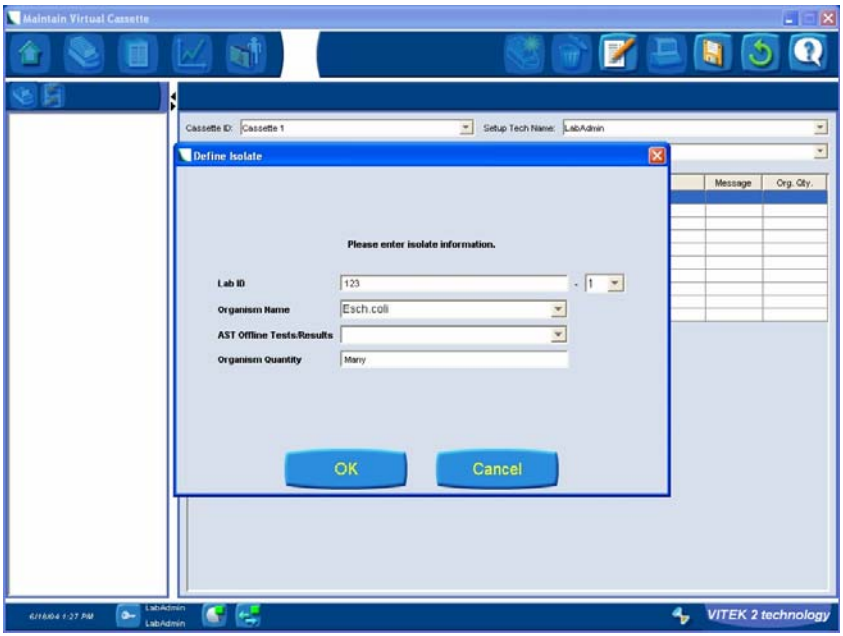

Figure 4-7: Define Isolate Window

Note: *You cannot enter Isolate information for card slots without bar codes.*

Saving Cassette Information

After you have defined all of the isolates in the cassette and entered all of the necessary information, you can save the cassette. To save the cassette:

1) After you have entered all of the necessary information into the system software, click **Save**.

Figure 4-8: Save Icon

2) If there are any inconsistencies, the system software will prompt you to make corrections before saving.

Note: *If the cassette is not defined properly, you will not be able to save the cassette.*

3) If everything is correct, the cassette is saved to the system software and the tests begin processing data. While saving, the system software will also complete card analysis.

Note: *During a save, the system software will also complete ID and AST analysis. This may take a minute.*

Printing Cassette Information

After defining a cassette, you can print the cassette layout.

1) Select the cassette that you want to view. The cassette appears in the workspace.

2) Click **Print** to print or preview the **Cassette Report**.

3) When you click **Print**, two options appear. You can select **Cassette Report** to get a report of the cassette setup information or Blank Cassette Worksheet.

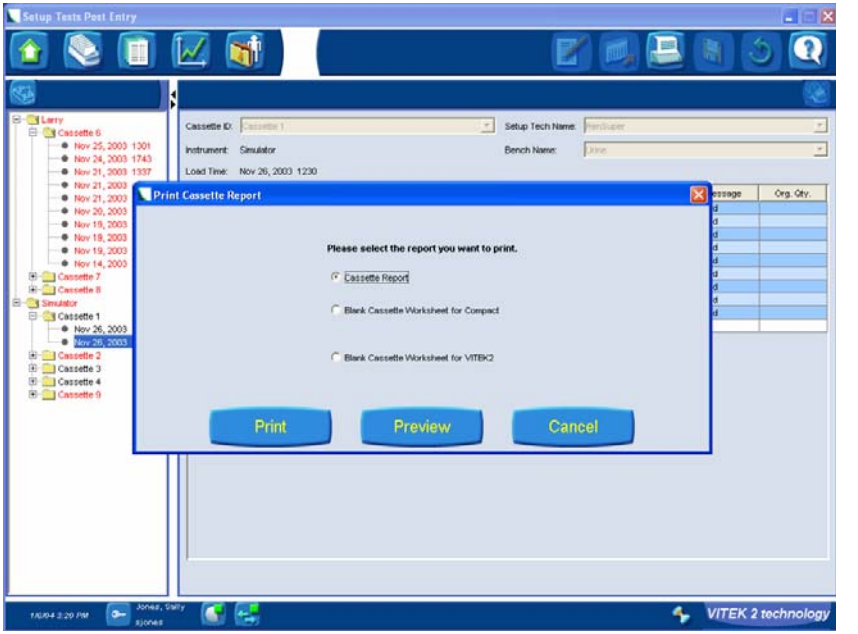

Figure 4-9: Print Cassette Report

Cassette Reports (Virtual, SCS or Post Entry)

You can print the isolate information related to the cassette by printing the cassette report.

Note: *A Cassette ID of 0 (zero) indicates that the instrument was not able to read the cassette bar code and the Cassette ID was not yet selected.*

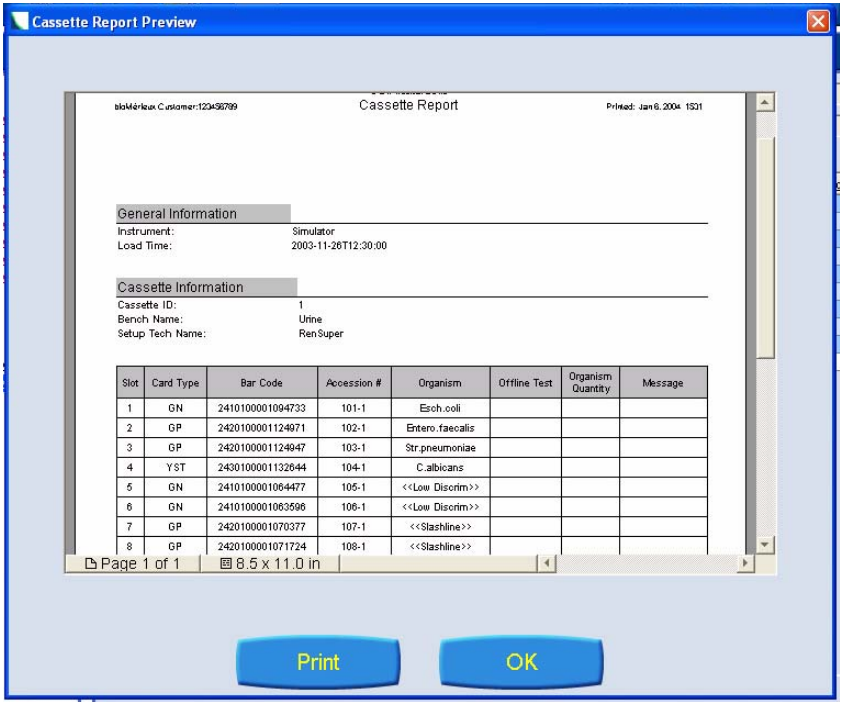
Cassette Report Preview
bioMérieux Customer:123456789
Cassette Report
Printed: Jan 6, 2004 1531
General Information
Instrument: Simulator
Load Time: 2003-11-26T12:30:00
Cassette Information
Cassette ID: 1
Bench Name: Urine
Setup Tech Name: RenSuper
Slot | Card Type | Bar Code | Accession # | Organism | Offline Test | Organism Quantity | Message
1 | GN | 2410100001094733 | 101-1 | Esch.coli
2 | GP | 2420100001124971 | 102-1 | Entero.faecalis
3 | GP | 2420100001124947 | 103-1 | Str.pneumoniae
4 | YST | 2430100001132644 | 104-1 | C.albicans
5 | GN | 2410100001064477 | 105-1 | <<Low Discrim>>
6 | GN | 2410100001063596 | 106-1 | <<Low Discrim>>
7 | GP | 2420100001070377 | 107-1 | <<Slashline>>
8 | GP | 2420100001071724 | 108-1 | <<Slashline>>
Page 1 of 1
8.5 x 11.0 in
Print
OK

Figure 4-10: Example Cassette Report

Blank Cassette Worksheet

From within the Setup Tests Post Entry view, you can print Blank Cassette Worksheets. Use a blank cassette worksheet to record isolate information during cassette setup. For an example, see Appendix A: Blank Cassette Worksheet.

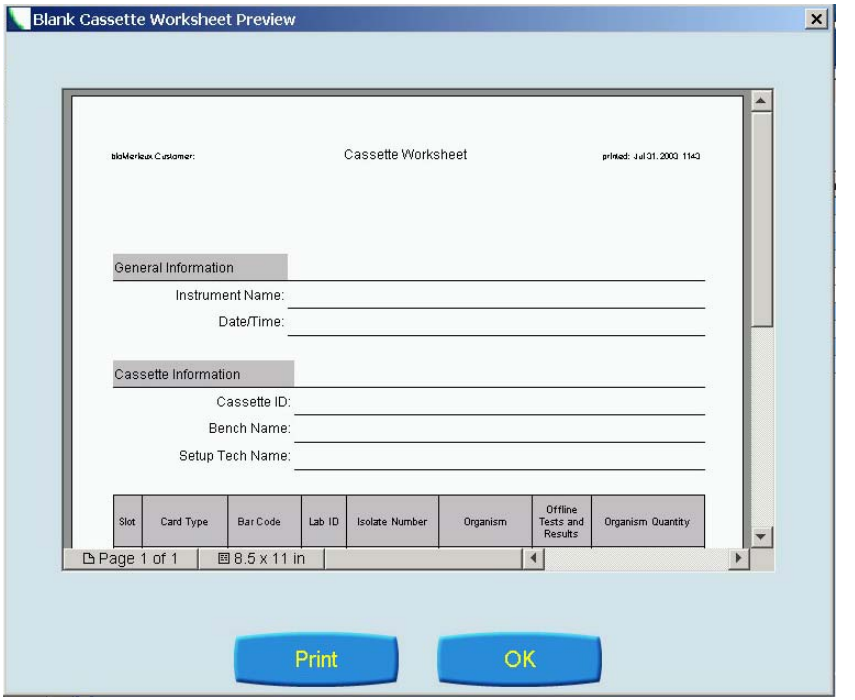

Figure 4-11: Example Blank Cassette Worksheet

Editing/Modifying Cassette Information

After you have defined and saved the cassette, you will only be able to make changes to the information from the View and Maintain Isolate Results view. However, if the cassette is a Virtual Cassette, you will be able to make changes until the cassette is loaded into the instrument. For details on viewing and maintaining isolate information, see Chapter 8 View and Maintain Isolate Results.

Ejecting Cards from Instrument

You can eject a card from the instrument at any time while in the Manage Cassettes view. To eject a card:

1) Select the *Cassette ID* from the navigation tree. The cassette will appear in the workspace.

2) Select the card that you wish to eject.

3) Click **Eject**.

Figure 4-12: Eject Icon

4) The system prompts you to confirm that you want to eject the card.

If you click **Yes,** the instrument will eject the card and the processing for that card will stop.

Using the Virtual Cassette Workflow

IMPORTANT: ***The Virtual Cassette workflow can only be used with a VITEK® 2 Compact instrument.***

From the navigation tree, click **Virtual Cassette** to switch your view from Actual Cassettes to Virtual Cassettes.

When a Virtual Cassette is loaded into the instrument, the cassette becomes an Actual Cassette and will move from the Virtual Cassette navigation tree to the Actual Cassette navigation tree.

Creating a Virtual Cassette

To enter information before loading the cassette into the instrument, you can create a virtual cassette. Creating a virtual cassette allows you to enter all of the necessary isolate information into the system software prior to loading the cassettes into the instrument. The instrument then reads the cards.

If the Actual Cassette matches the information that has already been entered for the Virtual Cassette, the cassette is saved as an Actual Cassette and is ready to receive further raw data from the instrument.

The Virtual Cassette information and isolate group definitions are stored within the system software. The system software then sends the Virtual Cassette definition to all attached instruments, so the instrument can match the Virtual Cassette with the Actual Cassette. This process is known as reconciliation. For details on viewing reconciliation details, see Viewing Reconciliation Details on page 4-19.

When you create a new Virtual Cassette, the blank virtual cassette workspace appears in the cassette workspace. The blank workspace displays all 10 cassette slots and input fields for each slot.

To begin setting up the Virtual Cassette:

1) From the Set Up Tests Post Entry window, click the **Maintain Virtual Cassette** icon located in the left view bar.

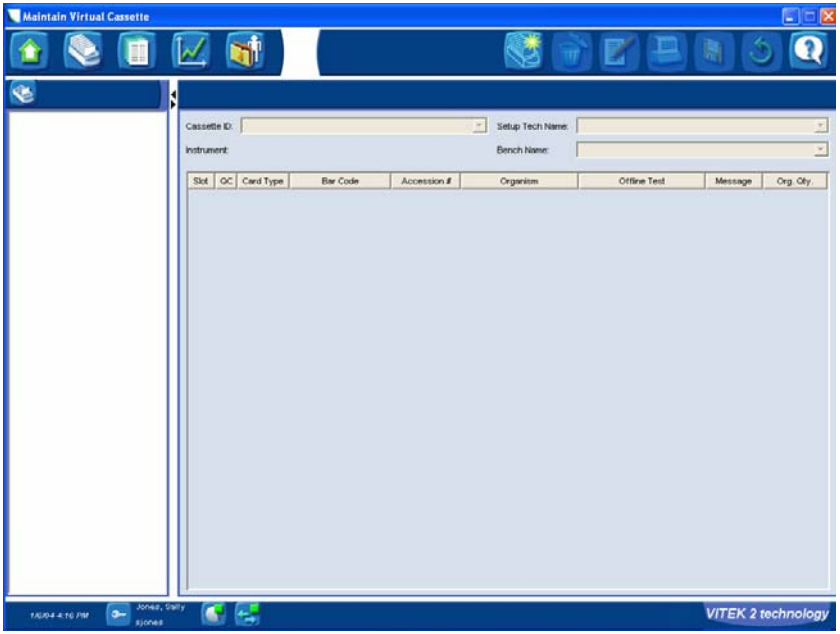

Figure 4-13: Maintain Virtual Cassette

2) Click the **Create New Virtual Cassette** icon.

Figure 4-14: Create New Virtual Cassette

3) The Virtual Cassette workspace area appears.

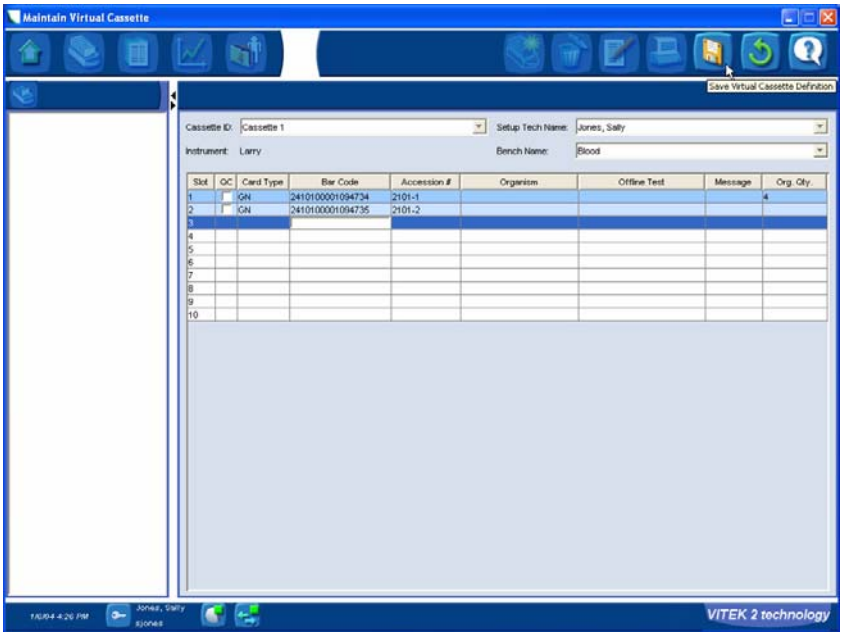

Figure 4-15: Virtual Cassette Workspace

4) Select a *Cassette ID* from the list of available Cassette IDs. The default Cassette IDs available are Cassette 1 through Cassette 9.

5) Select *your name* from the **Setup Tech** drop-down menu.

Note: *If 21 CFR 11 is enabled, the* **Setup Tech** *field is blank.*

6) If Bench Name is enabled in the configuration, select a *Bench Name* from the list benches where the cassette will be introduced.

7) Enter a bar code for each available slot, either by using the bar code scanner or by entering the bar codes manually from the workstation keyboard.

8) Enter the *Lab ID*.

9) Enter any offline test information.

10) Enter the *Organism Quantity*.

11) Link ID and AST cards to create isolate groups. Refer to Defining Isolate Group Information on page 4-10 for details. Enter the Organism ID here, if desired.

12) Click **Save** to save the new virtual cassette to the system software.

13) When the instrument processes the cards by reading the bar codes on the cards, the system matches the information with the data that you entered.

14) When the system confirms a match, the instrument processes the test cards.

15) If there is not a consistent match between the Virtual Cassette and the Actual Cassette, review the Reconciliation Details.

Viewing Reconciliation Details

Reconciliation consists of comparing the Virtual Cassette definition to the Actual Cassette definition loaded into the instrument. Any reconciliation problems detected by the Instrument are reported and you can view the reconciliation details on the system software.

To view the details, click the **View Reconciliation Details** icon.

Figure 4-16: View Reconciliation Failure Icon

Note: *The reconciliation details icon is only available when there is a reconciliation failure.*

Deleting a Virtual Cassette

If you have not loaded the cassette into the instrument, you can delete the pre-defined Virtual Cassette. To delete the virtual cassette:

1) Select a *Virtual Cassette* from the navigation tree.

2) Click **Delete Virtual Cassette**. A confirmation window appears.

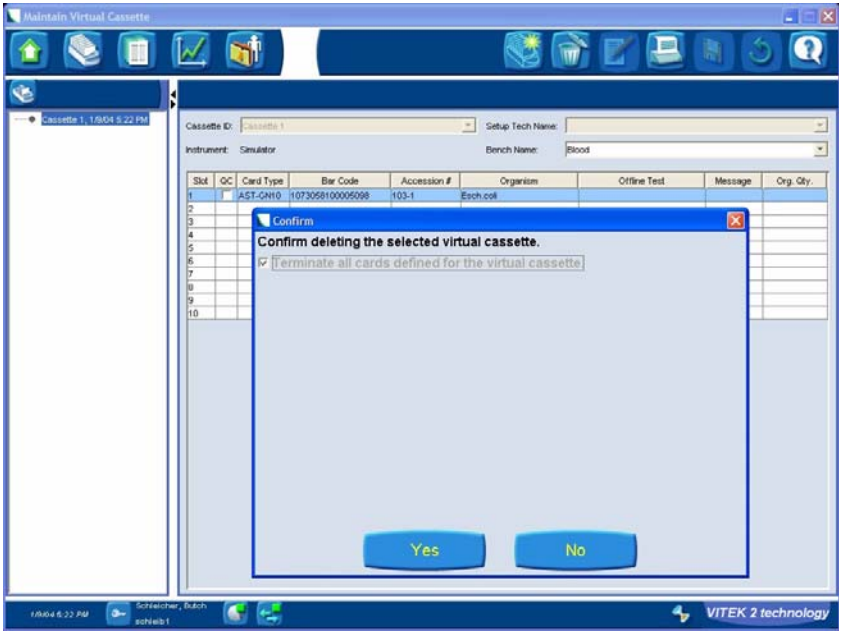

Figure 4-17: Delete Virtual Cassette

3) Select whether you want to terminate the tests that were set up for the deleted Virtual Cassette.

Note: *Terminating the test cards means you cannot reuse the test cards that were set up with that particular Virtual Cassette.*

4) The Virtual Cassette definition is deleted.

5) The *Virtual Cassette ID* is now available for reuse since the system deleted the definition for that ID.

Using the Smart Carrier Station (SCS)

IMPORTANT: The Smart Carrier Station workflow can only be used with a VITEK® 2 Instrument.

The Smart Carrier Station (SCS) is an independent piece of hardware that allows you to define cassette and isolate information prior to loading a cassette into a VITEK® 2 Instrument. A cassette created with a Smart Carrier Station will retain all user defined isolate information and can be transferred and read by a VITEK® 2 instrument. The VITEK® 2 instrument will identify the information from a Smart Carrier Station cassette and transfer the data to the VITEK® 2 Systems software. The VITEK® 2 Systems software will automatically link ID and AST cards from Smart Carrier Station cassettes using the Lab ID and isolate number.

This workflow outlines all of the steps required to prepare a specimen and a VITEK® 2 card, and to process that card through the VITEK® 2 instrument, using the Smart Carrier Station.

1) Prepare a pure culture of the organism, according to the Culture Requirements Table.

2) Use the VITEK® 2 DENSICHEK to prepare the appropriate organism suspension.

3) Take the suspension to the Smart Carrier Station.

4) Make sure that all configuration items on the SCS are set correctly. (See the VITEK® 2 Instrument User Manual.)

5) Enter the data for the culture and the test card, and place the suspension test tube and the test card in the appropriate slot of the cassette. (See the VITEK® 2 Instrument User Manual.)

6) Repeat Step 5 for the other suspensions and test cards for this cassette.

7) Remove the cassette from the SCS, and take it to the VITEK® 2 instrument.

For systems using a Smart Carrier Station, each cassette is fitted with a special memory chip, called the button memory. When a cassette is on a Smart Carrier Station, the button memory stores the information that you enter for each test card. This information is read by a station in a VITEK® 2 instrument, which marks the memory chip as being read, allowing the cassette to be reused.

8) Place the cassette into the Cassette Load station, and close the door.

The VITEK® 2 instrument scans the card bar codes to detect any problems (expired cards, card type that could not be determined, etc.).

Smart Carrier Cassette Information

Once a Smart Carrier Station cassette has been read by a VITEK® 2 instrument and isolate and the cassette definition have been transferred to the workstation, you can process and manage that cassette with the VITEK® 2 Systems software. The VITEK® 2 instrument sends the cassette definition, including isolate information to the workstation.

A reconciled SCS cassette transferred to the workstation will include the following:

- Cassette ID
- SCS Bench Name (if enabled in configuration)
- SCS Setup Tech User ID
- Accession ID
- Card Bar Code

Note: *A cassette appears in red in the navigation tree when additional information is needed to completely define the selected cassette.*

Managing Smart Carrier Station Cassettes

SCS Setup Technologist ID

The VITEK® 2 Systems software will attempt to identify the full name of the original Setup Technologist based on the **SCS Setup Technologist User ID** received from a Smart Carrier Station. If an exact match (case sensitive) is not found, the system will display **???**. If 21CFR 11 is enabled, only a lab supervisor can edit the Setup Technologist associated with a Smart Carrier Station cassette after the cassette data has been transferred to the workstation. If 21 CFR 11 is disabled, any user can edit the field.

To edit the Setup Technologist ID:

1) From the **Set Up Tests Post Entry** view, select a cassette from the navigation tree.

The cassette you selected appears in the cassette workspace.

2) Select one of the available names from the of **Setup Technologist** drop-down field.

3) After you have entered all of the necessary information into the system software, click **Save**.

The Workstation logs the event for each isolate in the cassette if the name of the Setup Technologist changes. If 21 CFR 11 is enabled, the cassette will remain incomplete until a Setup Technologist is assigned.

Note: *If 21 CFR 11 Compliance Mode is enabled, the name of the Laboratory Technologist logged onto the Workstation when the cassette was loaded in the instrument will be used for the Setup Technologist Name field.*

Note: *If 21 CFR 11 is enabled in general configuration, the laboratory technologist should be logged into the workstation before loading a cassette.*

Bench Name (if enabled in general configuration)

The VITEK® 2 Systems software will attempt to identify the **Bench Name** based on the Bench Name received from a Smart Carrier Station. If an exact match (case sensitive) is not found, the system will display **???**. You can edit the Bench Name associated with a Smart Carrier Station cassette after the cassette information has been transferred to the workstation.

To edit the Bench Name:

1) From the **Set Up Tests Post Entry** view, select a cassette from the navigation tree.

The cassette you selected appears in the cassette workspace.

2) Select one of the available names from the of **Bench Name** list.

3) After you have entered all of the necessary information into the system software, click **Save**.

Note: *If the Bench Name option is enabled in the general configuration settings, the cassette will remain incomplete until a Bench Name is assigned.*

Cassette ID

If the system software receives a cassette with a blank Cassette ID entry, the workstation will display “SCS” as the default Cassette ID.

Note: *The Cassette ID field cannot be edited.*

Setting Up and Entering Quality Control (QC) Information

To set up a Quality Control (QC) Test for new card shipments:

1) When defining isolate groups, select the **check box** beside the card slot that you want to designate as a QC test.

2) The system software verifies that the card is part of a QC shipment.

3) If a shipment was already created for this lot, the Set Up QC Test window appears. If a shipment was not created for this card lot, the Record Shipment window appears.

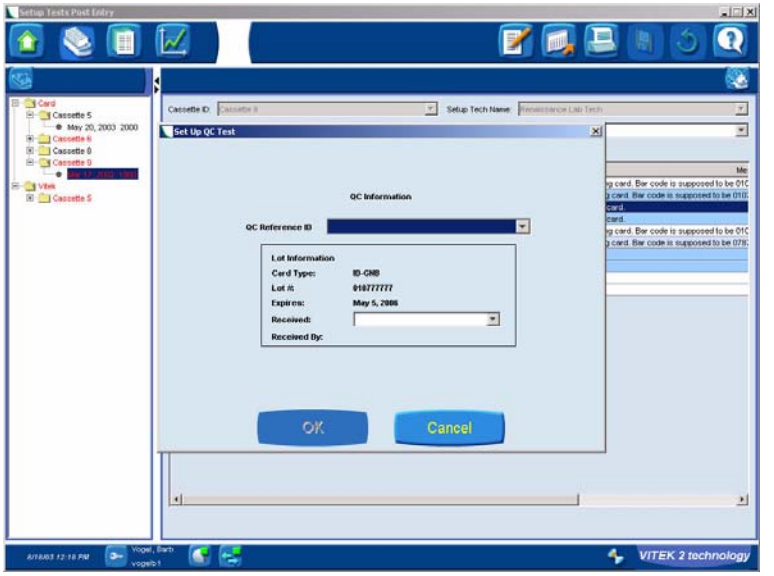

Figure 4-18: Set Up QC Test Window

4) Select the *QC Reference ID* from a list of QC Reference IDs and associated organism names appropriate for the card type of the selected card.

For Example: ATCC25922 | *E.coli*

Note: *QC Reference IDs can be selected from a list.*

5) The following associated QC information appears:

- Card Type
- Card Lot Number

- Card Expiration Date
- Card Received Date (if only one shipment for lot number)
- Technologist's name (laboratory technologist who entered lot information)

6) If more than one shipment was recorded for the lot number, the system prompts you to select a *Received Date* from a list to select a specific shipment.

7) The following QC information associated with the selected card appears:

- **Expected organism** (for AST cards and Workstation Key ID Organism)

8) When all information is entered and associated, click **OK**.

9) The Set Up QC Test window closes, and the cassette display updates.

Note: *QC Isolate groups contain only one card, either an AST or an ID card.*

For details on managing QC results, see Chapter 7 Maintain Customer Quality Control

MANAGE PATIENT INFORMATION (CLINICAL USE) 5

About This Chapter

This chapter describes viewing, managing, and linking patient and specimen information.

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Adding Patients • 5-3
Adding Specimens • 5-4
Linking Isolate and Patient Information • 5-4
Linking Specimens to an Existing Isolate • 5-5
Creating a Specimen Before an Isolate Exists • 5-5
Data Management Download • 5-6
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Viewing and Filtering Patient and Specimen Information

To view and maintain patient information:

1) From the Main view or from the navigation bar, click **Enter Manage Patient Information view**.

Figure 5-1: Enter Manage Patient Information View

2) The View and Maintain Patient Information view appears.

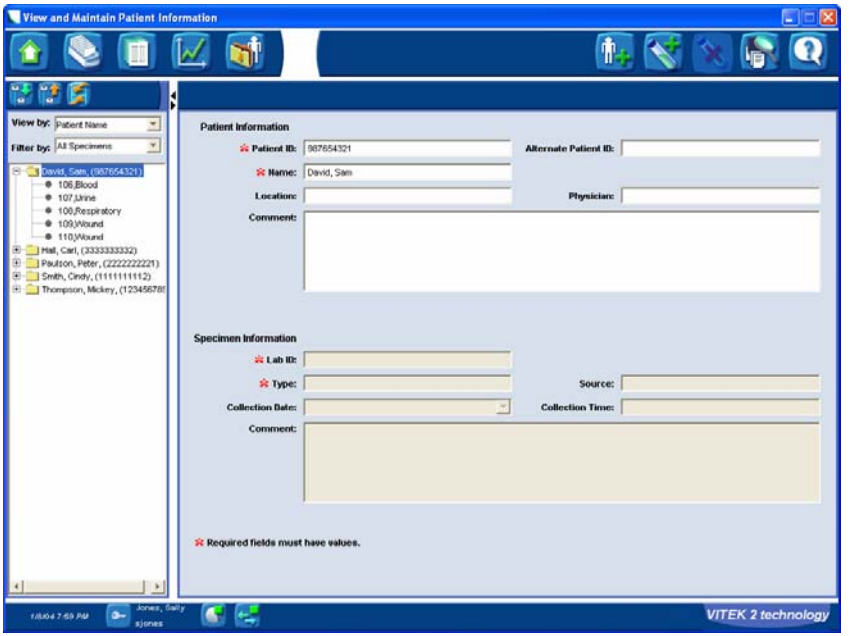

Figure 5-2: View and Maintain Patient Information

3) You can view by and filter by the patients and specimens that appear in the navigation tree.

4) From the first drop-down list that appears in the navigation tree, select whether you want to view by **Patient Name** or **Patient ID**.

5) From the second drop-down list, select whether you want to see All Specimens, Only Specimen With Isolates, or Only Specimens Without Isolates.

Adding Patients

When you view and maintain patient information, you can add patients to the system software.

1) From the View and Maintain Patient Information view, click **Add Patient.**

Figure 5-3: Add Patient/Specimen Icon

2) Enter the patient information in the Add Patient window.

Note: *The patient must have a unique ID and an alternative unique ID.*

3) Fill in the following fields:

- Patient ID (required and must be unique)
- Alternate Patient ID (must be unique)
- Name (required)
- Location
- Physician
- Comments

Note: *You can enter the specimen information at the same time. For details on entering specimen information, see* *Adding Specimens on page 5-4**.*

Note: *You cannot add a patient without adding a specimen. If a patient has already been entered with one or more specimens you can always enter additional specimens, but you cannot enter a patient without an associated specimen.*

Adding Specimens

When you view and maintain patient information, you can add more than one specimen to a patient that has already been entered. To do so follow these steps:

1) From the View and Maintain Patient Information view, select the patient and click **Add Specimen.**

Figure 5-4: Add Specimen Icon

2) Enter the *Specimen information* in the Add Patient/Specimen window.

3) Fill in the following fields:

- Lab ID (required)
- Type (required): for example, Blood, Urine, Wound, etc.
- Source: for example, right lower leg, etc.
- Collection Date
- Collection Time
- Comments

Linking Isolate and Patient Information

Patient demographics must be enabled from within user configuration to maintain the association between isolates and specimens in the active workspace. For details, see Chapter 10 General Configuration.

When a patient record is created, the system software attempts to link the patient with one or more isolates in the active workspace using the Laboratory Identification Number (Lab ID).

The same is true when an isolate is created. The system software will attempt to link the isolate with a single patient in the active workspace. This linking is not associated with isolates or patient information in the inactive workspace.

When an isolate or a specimen is created, modified, or deleted as a result of a data management download, the isolate and patient information are linked by the Laboratory Identification Number (Lab ID) of the isolate and the Laboratory Identification Number (Lab ID) of the specimen. If the isolate Lab ID is not found, the isolate is flagged as qualified in the View and Maintain Isolate Results view.

Linking Specimens to an Existing Isolate

When you set up test cards post entry, use the Smart Carrier Station or Virtual Cassette workflow, follow these steps to link a specimen to an existing isolate.

1) Enter the Isolate Information from the Blank Cassette Worksheet. For details on setting up tests, see Chapter 4 Using the Set Up Tests Post Entry Workflow.

2) If Patient demographics is enabled in General Configuration, an isolate without patient information will result as a qualified isolate.

3) To complete this isolate, link the isolate to patient and specimen information.

Note: *You can link one or more isolates to a specimen.*

4) If the Lab ID matches the Isolate Lab ID, the software automatically establishes this link.

Note: *Be sure to enter the correct Lab ID. If the Lab ID is incorrect, the isolate will result as a qualified isolate and will not be automatically linked to the appropriate specimen.*

Creating a Specimen Before an Isolate Exists

1) From the View and Maintain Patient Information window, manually type the specimen information or download the information from the LIS (external data management system).

2) When the cassette with the matching isolate Lab ID is input into the instrument and system software, the system software uses the Lab ID to automatically link the isolate and specimen information.

Note: *Be sure to enter the correct Lab ID. If the specimen created uses the wrong Lab ID, then the specimen does not automatically link to the appropriate isolate.*

Data Management Download

When patient information is downloaded from a data management system, the isolate and patient information are linked by the Lab ID. If there is no match for the isolate Lab ID and the specimen Lab ID, the Isolate becomes qualified in the View and Maintain Isolate Results window. For details on connecting to a data management system to download information using a Bi-directional Communication Interface application known as BCI, see Chapter 12 Configure and Maintain BCI.

Deleting Specimens

If you want to delete a specimen, select the specimen in the navigation tree and click **Delete** Specimen.

Note: *If the specimen is the last specimen for a particular patient, the software asks you to confirm the deletion of both the patient and the specimen because you cannot have a patient without associated specimens.*

Moving Specimens

You can move a Specimen by using the drag and drop technique. Click on the specimen in the navigation tree and hold the mouse button down while dragging the specimen to a different patient in the navigation tree.

Note: *Be sure to associate the specimen with the correct patient. Moving a specimen is typically used when a laboratory technologist incorrectly associates a specimen with the wrong patient.*

Searching Inactive Reports

After an isolate associated with a patient specimen has aged, the patient information automatically becomes inactive. The number of days an isolate will remain in the active workspace before it becomes aged depends on your configuration settings. To search for inactive reports:

1) From the View and Maintain Patient Information window, click **Search Inactive Reports**.

Figure 5-5: Search Inactive Reports Icon

2) The Search Inactive Reports window appears.

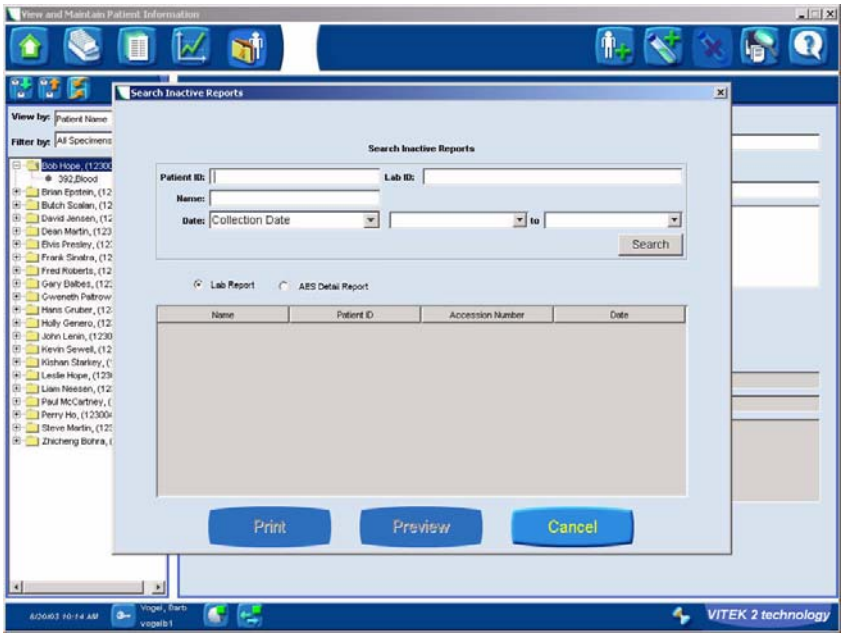

Figure 5-6: Search Inactive Reports Window

3) Enter your search criteria by filling out the fields.

Note: *If you choose a specific date range in the available date fields and the inactive isolate you are searching for did not previously have a collection date associated with it, the search results will not display that isolate in the Search for Inactive Results window. To see results for inactive isolates that did not have an assigned collection date, leave the date range fields empty. Inactive isolate search results that did not have an initial collection date will not display data in the Date column.*

4) Click **Search**. The inactive reports that match closest to your search criteria appear in the Search for Inactive Reports window.

5) Select and/or scroll to select from the list of results and select the result you want to view.

6) Choose the report format that you wish to display by selecting a report option.

- **Lab Report** (Default)
- **AES Detail Report**

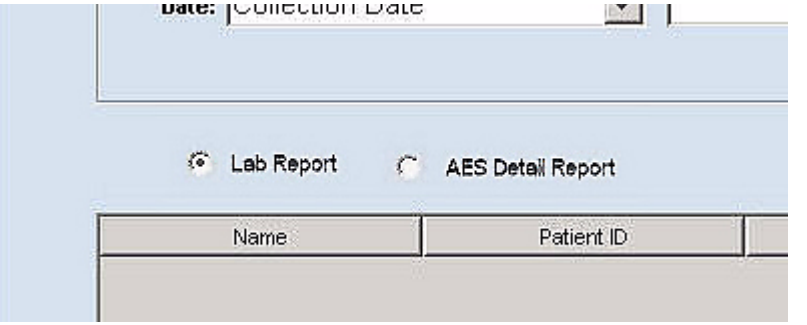

Figure 5-7: Inactive Reports Format Options

7) Click **Preview** to display the inactive report and view the details.

8) Click **Print** to print the report to the workstation printer.

Printing Reports

To print lab reports for isolates aged from the active workspace, follow these steps:

1) From the Search Inactive Reports window, click **Preview** to preview the report based on your search criteria.

2) The Preview Report window appears.

3) Click **Print** to print the report to the workstation printer.

MAINTAIN SUPPLEMENTAL REACT FILE (INDUSTRIAL USE) 6

About This Chapter

This chapter introduces and describes maintaining the supplemental reaction file (SRF).

Chapter Contents

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Copy Biopatterns to SRF • 6-2
Criteria for Merging ID Results with SRF Results • 6-4
Creating and Maintaining SRF Organisms (Supervisor) • 6-5
Viewing and Maintaining SRF Data • 6-5
Creating SRF Organisms • 6-7
Viewing and Maintaining SRF Organism Information • 6-9
Deleting SRF Organisms • 6-9
Maintaining Unassociated SRF Biopatterns • 6-9
Viewing Unassociated Biopatterns • 6-10
Deleting an Unassociated SRF Biopattern • 6-10
Linking/Associating Biopatterns with SRF Organisms • 6-11
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Unassociating Biopatterns from SRF Organisms • 6-13
View SRF Biopattern Associations for an Existing SRF Organism • 6-14
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Printing the SRF Biopattern Report • 6-15

Introduction to SRF (Industry Use)

Note: *From General Configuration, the system software must be set to* ***Industry Mode*** *and* ***SRF*** *must be enabled to work with SRF data. For details, see* *General Configuration on page 10-4**.*

The system software interprets organism identification from biochemical test results using a set of claimed organisms/reactions. For situations where the organism identification meets a certain criteria set by the individual laboratory, you can do the following:

- **Copy to SRF —** Copy the biopattern to a supplemental reaction file (SRF). This supplemental file includes a set of organism definitions known as SRF Organisms.
- **Associate a biopattern to SRF organisms —** The SRF biopattern can be associated to the SRF organism to result in a SRF organism call.
- **Activate the SRF Organism —** When 10 SRF biopatterns are associated with the SRF Organism, you may activate the SRF Organism for use by the system software during ID analysis.

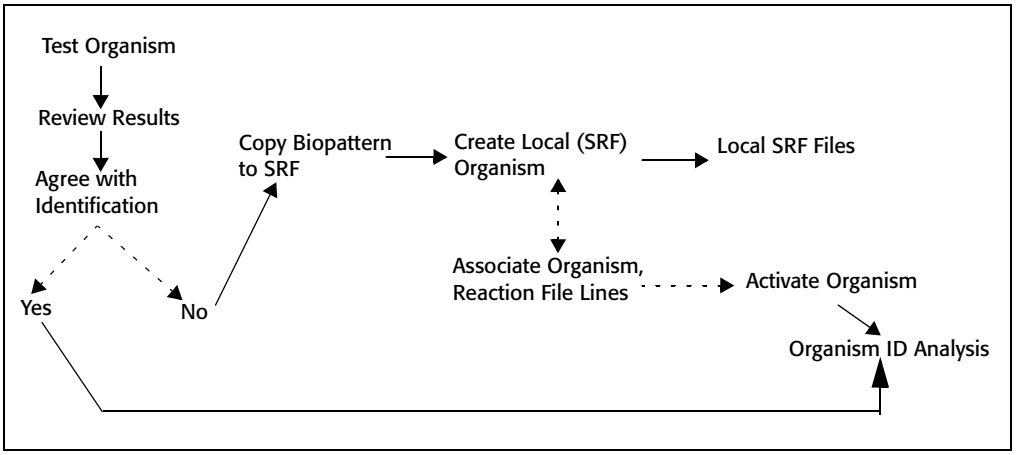

Figure 6-1: SRF Workflow Diagram

Copy Biopatterns to SRF

Note: *Any laboratory technologist or supervisor can copy biopatterns to the SRF database; however, only a supervisor can view and maintain the SRF database information.*

When you review organism identification results and the organism meets certain criteria, you can copy the biopattern to the local database known as the SRF Database stored in the system software. The criteria for copying biopatterns to the database, depends on the needs of your individual laboratory.

Note: *If the identification card selected to copy to SRF is part of an isolate group, the isolate group results status must be* ***final****.*

To copy the Biopattern to the SRF Database:

1) From View and Maintain Isolate Results view, select the ID results that you want to copy to SRF and click **Send to SRF**.

Figure 6-2: Send to SRF Icon

2) A confirmation window appears asking you to confirm copying this biopattern to SRF. Click **Yes** to copy the biopattern.

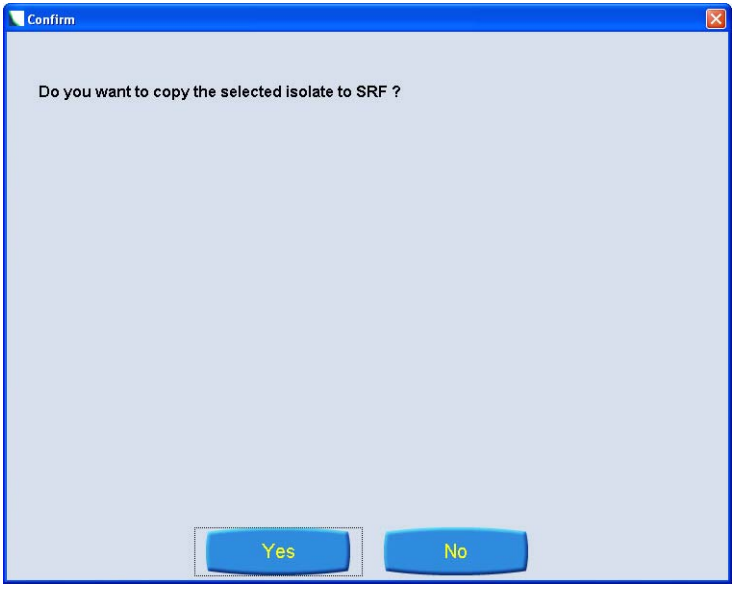

Figure 6-3: Copy Biopattern Window

3) The following isolate information is recorded in the local SRF database as an SRF Biopattern:

- Card type
- Bionumber
- Biopattern (biochemicals and reactions)
- Organism Name
- Card bar code
- Accession ID
- User ID (user who copied Biopattern to SRF)
- Date copied to SRF

Note: *If the card bar code has already been entered, an informational message appears and the system does not update SRF.*

4) To view the SRF Organism, go to the Maintain SRF Data window. For more details, see Creating and Maintaining SRF Organisms (Supervisor) on page 6-5.

Criteria for Merging ID Results with SRF Results

The criteria for copying biopatterns to the database depends on the needs of your individual laboratory. Any of the following ID Analysis Results may be copied to SRF:

- Unidentified
- Single Excellent Identification
- Low Discrimination
- Slashline

Creating and Maintaining SRF Organisms (Supervisor)

Viewing and Maintaining SRF Data

When the system software is configured for Industry Mode, you can access the SRF view by following these steps:

1) From the Main view, click the **SRF** icon to access the Maintain SRF Data view.

2) The Maintain SRF Data view appears.

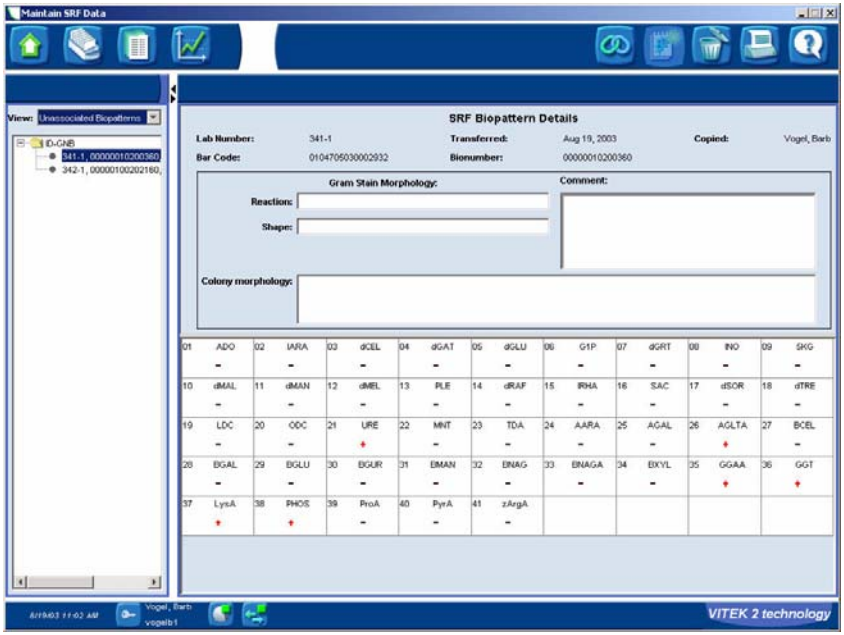
MainLain SRF Data
View: Unassociated Biopatterns
ID-GNB
341-1, 0000010200360
342-1, 0000010202160,
SRF Biopattern Details
Lab Number: 341-1
Transferred: Aug 19, 2003
Copied: Vogel, Barb
Bar Code: 0104705030002932
Bionumber: 0000010200360
Gram Stain Morphology:
Reaction:
Shape:
Comment:
Colony morphology:
01 ADO - 02 IARA - 03 dCEL - 04 dGAT - 05 dGLU - 06 G1P - 07 dGRT - 08 INO - 09 SKG -
10 dMAL - 11 dMAN - 12 dMEL - 13 PLE - 14 dRAF - 15 IRHA - 16 SAC - 17 dSOR - 18 dTRE -
19 LDC - 20 ODC - 21 URE + 22 MNT - 23 TDA - 24 AARA - 25 AGAL - 26 AGLTA + 27 BOEL -
28 BGAL - 29 BGLU - 30 BGUR - 31 BMAN - 32 BNAG - 33 BNAGA - 34 BXYL - 35 GGAA + 36 GGT +
37 LysA + 38 PHOS + 39 ProA - 40 PyrA - 41 zArgA -
Vogel, Barb
vogelb1
VITEK 2 technology

Figure 6-4: View and Maintain SRF Data View

3) From the Maintain SRF Data view, you can:

- Associate the SRF organism to an Unassociated biopattern
- Create an organism.
- Delete the SRF organism
- Print the SRF Report

4) You can view the following SRF Data from the navigation tree:

- Unassociated Biopatterns

- SRF Organisms (must have 10 biopatterns associated with SRF organisms to activate).

Note: *If SRF Organisms are not yet created, no information appears on the SRF organism view.*

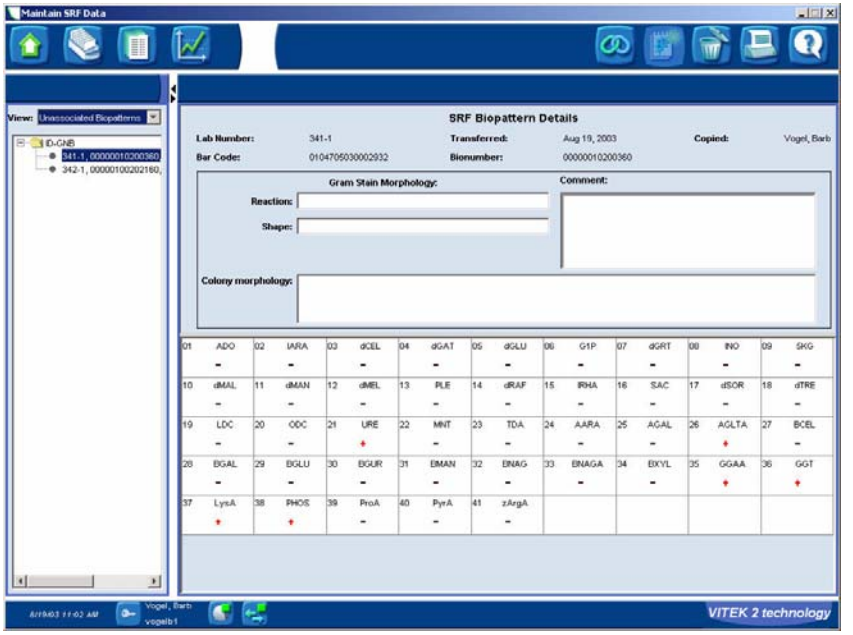
Maintain SRF Data
View: Unassociated Biopatterns
ID-GNB
341-1, 00000010200360
342-1, 00000010202180,
SRF Biopattern Details
Lab Number: 341-1
Transferred: Aug 19, 2003
Copied: Vogel, Barb
Bar Code: 0104705030002932
Bionumber: 00000010200360
Gram Stain Morphology:
Reaction:
Shape:
Comment:
Colony morphology:
01 ADO - 02 IARA - 03 dCEL - 04 dGAT - 05 dGLU - 06 G1P - 07 dGRT - 08 INO - 09 SKG -
10 dMAL - 11 dMAN - 12 dMEL - 13 PLE - 14 dRAF - 15 RHA - 16 SAC - 17 dSOR - 18 dTRE -
19 LDC - 20 ODC - 21 URE + 22 MNT - 23 TDA - 24 AARA - 25 AGAL - 26 AGLTA + 27 BCEL -
28 BGAL - 29 BGLU - 30 BGUR - 31 BMAN - 32 BNAG - 33 BNAGA - 34 BXYL - 35 GGAA + 36 GGT +
37 LysA + 38 PHOS + 39 ProA - 40 PyrA - 41 zArgA -
Vogel, Barb
vogelb1
VITEK 2 technology

Figure 6-5: Unassociated Biopattern View

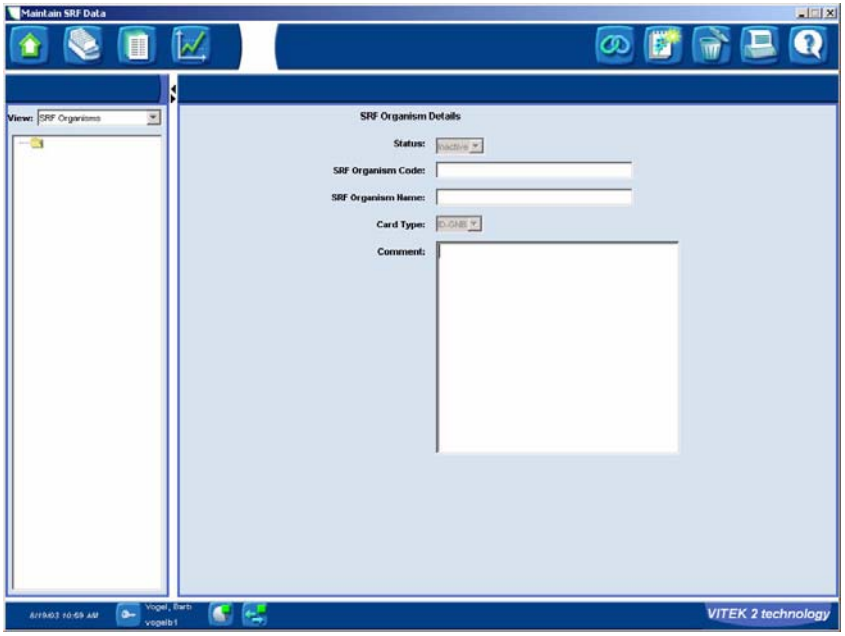

Figure 6-6: SRF Organism View

Creating SRF Organisms

Note: *You must be a Supervisor to create a new SRF organism.*

1) From the Maintain SRF Data view, in the navigation tree select **SRF Organism** from the **View** drop-down list.
2) The SRF Organism view appears.
3) Click the **Create SRF Organism** icon.

Figure 6-7: Create SRF Organism

4) The Create SRF Organism window appears.

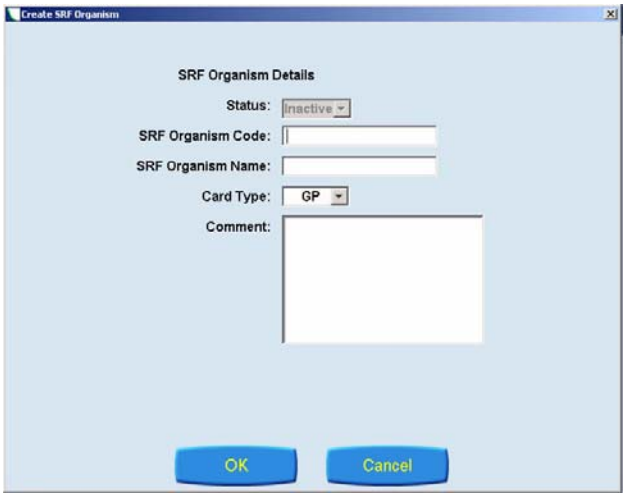

Figure 6-8: New SRF Organism Window

5) Enter the information described in the following table.

Table 6-1: SRF Organism Definition Window

Field	Description
Status	Active: SRF Organism has already been activated for use on identification analysis. Inactive: The SRF Organism has not yet been activated for use on identification analysis.
SRF Organism Code	Type a unique, user-defined code that identifies the SRF Organism. The code is limited to four alpha characters.
SRF Organism Name	A user-defined name of the SRF organism.
Card Type	Type of card the identification analysis was recorded on.
Comment	Enter an informational comment (optional).

Note: *Be sure to enter a unique new organism code. If the code already exists, the SRF organism is not entered and the SRF database is not updated.*

Note: *You must have 10 biopatterns associated with SRF organisms to activate the SRF organism.*

6) Click **OK**.

Viewing and Maintaining SRF Organism Information

As a supervisor you can maintain SRF organism information. From the Maintain SRF view:

1) From the Maintain SRF Data view, select **SRF Organism** from the **View** drop-down list.

2) Select the specific SRF Organism that you would like to view.

3) The following information displays:

- SRF Organism Activation Status (upon creation, default is inactive)
- SRF Organism Code
- SRF Organism Name
- Associated identification card type
- SRF Organism Comment

Deleting SRF Organisms

To delete SRF Organisms:

1) From the Maintain SRF Data view, select **SRF Organisms** from the **View** drop-down list.

2) Select *SRF Organism* in the displayed list.

Note: *If SRF organism is linked to an isolate in the active workspace, you cannot delete the SRF organism.*

3) Click **Delete.**

4) Deleting the SRF Organism also deletes all associated biopatterns. The software asks you to confirm deletion of the SRF Organism. Click **Yes** to confirm.

5) The selected *SRF Organism* is removed from the SRF database.

Maintaining Unassociated SRF Biopatterns

When you are viewing and maintaining the unassociated SRF biopatterns, the workstation displays the unassociated SRF biopattern workspace, listing unassociated SRF biopatterns identified by bionumber, and grouped by card type.

Viewing Unassociated Biopatterns

To view the unassociated biopatterns:

1) From the Maintain SRF Data view, select **Unassociated SRF Biopatterns** from the **View** drop-down list.
2) Select an individual SRF biopattern from the list in the navigation tree.
3) The workstation displays information about SRF Biopattern:
   - Lab Number
   - Card bar code
   - Date transferred or copied to SRF
   - Bionumber
   - User ID who copied biopattern to SRF
   - Gram Stain Morphology

     Gram Stain Reaction (positive, negative, variable, etc.)
     Shape (cocci, rod, coccobacillus, etc.)
   - Comment
   - Colony Morphology (free text)
   - SRF Biopattern (list of biochemicals and reactions)
4) Add information to available fields, if necessary. The system software is updated to reflect the changes.
5) For details on linking unassociated biopatterns to SRF Organisms, see Linking/Associating Biopatterns with SRF Organisms on page 6-11.

Deleting an Unassociated SRF Biopattern

1) From the Maintain SRF Data view, select **Unassociated SRF Biopatterns** from the **View** drop-down list.
2) Select an individual SRF biopattern from the list in the navigation tree.
3) Click **Delete.**

Figure 6-9: Delete Icon

4) A confirmation window appears asking you to confirm the deletion of the unassociated SRF biopattern. Click **Yes** to confirm.

5) The unassociated SRF biopattern is removed from the SRF database.

Linking/Associating Biopatterns with SRF Organisms

An unlimited number of SRF biopatterns can be associated with SRF organisms. Once the SRF organism has 10 SRF biopatterns associated with it, the SRF organism is eligible for activation. For details on activating SRF Organisms, see Activating SRF Organisms on page 6-14.

Note: *SRF biopatterns can be left unassociated.*

Associating a Biopattern to an Existing Organism

To associate SRF biopattern to an existing SRF organism:

1) Select the SRF organism in the displayed list, and click **Maintain SRF Organism Association**.

Figure 6-10: Maintain SRF Organism Association Icon

2) The Maintain SRF Association view appears.

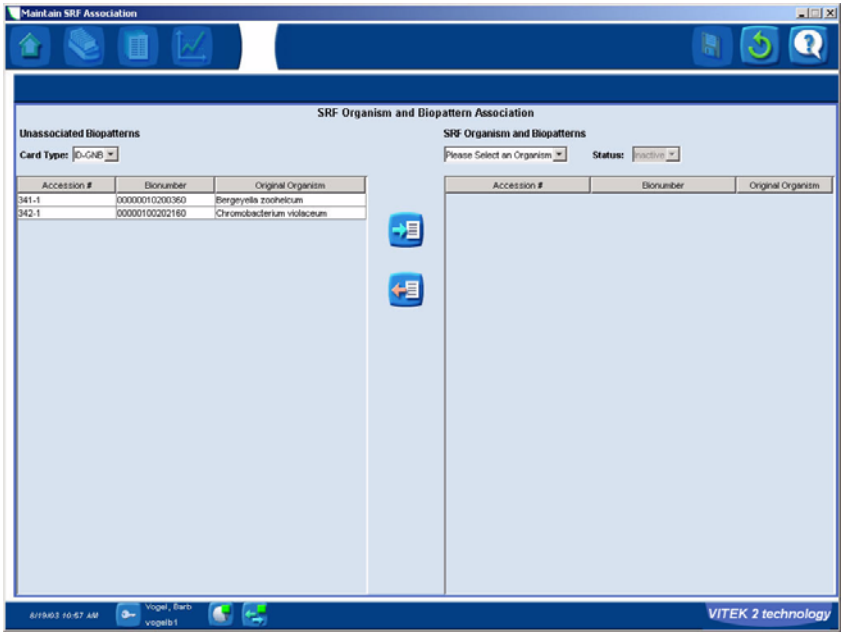

Figure 6-11: Maintain SRF Association View

3) Select the SRF organism that you want to associate to the biopattern or select the biopattern you want to associate.

Note: *You can use Shift or Ctrl to select multiple biopatterns.*

4) Select an **Organism** from the drop-down menu.

5) Click the **Associate Biopattern/SRF Organism** icon.

Figure 6-12: Associate Biopattern/SRF Organism Icon

6) Repeat selection and association if desired.

7) Click **Save**.

8) The system software is updated and the biopattern is now associated with SRF Organism.

Unassociating Biopatterns from SRF Organisms

To unassociate the SRF biopattern from an existing SRF organism:

1) From the Maintain SRF Associations view, select **SRF Organism**.
2) Select the SRF biopattern in the displayed list, and click the **Maintain SRF Organism Association** icon.
3) The Maintain SRF Association view appears.

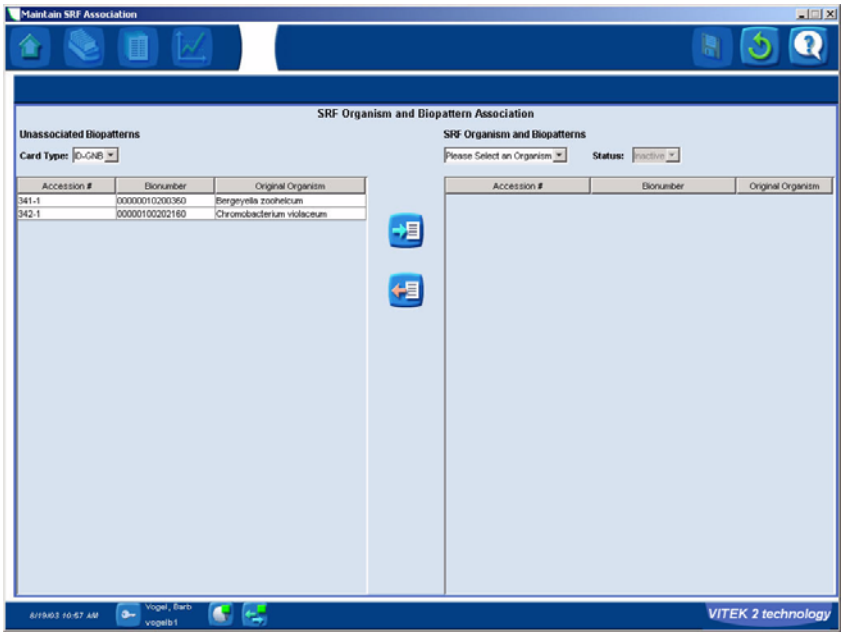

Figure 6-13: Maintain SRF Association View

4) Select an **Organism** from the drop-down menu.
5) Select the bionumber you want to unassociate and click **Unassociate Biopattern/SRF Organism**.

Figure 6-14: Unassociate Biopattern/SRF Organism Icon

6) Click **Save**.

7) The system software is updated and the biopattern is no longer with the SRF Organism.

View SRF Biopattern Associations for an Existing SRF Organism

1) Select SRF organism displayed in the list.

2) The associated SRF biopatterns are listed under the organism name in the navigation tree. The following information displays in the navigation tree:

- Accession #
- Bionumber (read-only)

3) The following information displays in the workspace:

- Status
- SRF Organism Code
- SRF Organism Name
- Card Type
- Comment

4) Selecting a displayed bionumber displays the SRF Biopattern Details.

Activating SRF Organisms

You can activate SRF organisms when the organism reaches the minimum number of associated SRF biopatterns. The minimum number of associated biopatterns is 10.

To activate the SRF organism:

1) Select the SRF Organism in the displayed list.

2) If there are 10 or more biopatterns associated to the selected SRF organism, the **Status** drop-down list is no longer grayed out, and you can elect to activate the SRF organism to make the organism available for ID analysis.

3) Select the **SRF Organism** and select **Active** from the **Status** drop-down list. This makes the SRF organism available for ID analysis.

Note: *If the SRF organism has not met the minimum number of associated SRF biopatterns, you cannot change the status of the SRF organism to Active.*

Deactivating SRF Organisms

To deactivate the SRF organism at any time:

1) Select an SRF organism displayed in the list.

2) Select **Inactive** from the **Status** drop-down list.

3) Confirm whether you want to deactivate the SRF Organism.

4) If you click **Yes**, the SRF Organism becomes deactivated.

Printing the SRF Biopattern Report

When you select the SRF organism from the displayed list you can elect to print the existing SRF Organism and its associated SRF biopatterns:

1) From the Maintain SRF Data view, select *SRF Organisms* from the **View** drop-down list.

2) Select the SRF organism displayed in the list.

3) Select **Print** to print the selected SRF biopattern report for each SRF biopattern associated with the selected SRF organism.

4) The SRF Organism Report view appears.

5) Click **Print** to print the report to the workstation printer.

6) Click **OK** to return to the Maintain SRF Data view.

SRF Organism Report (Industrial Use)

The SRF Organism report allows you to print information related to the SRF organism and its associated biopatterns.

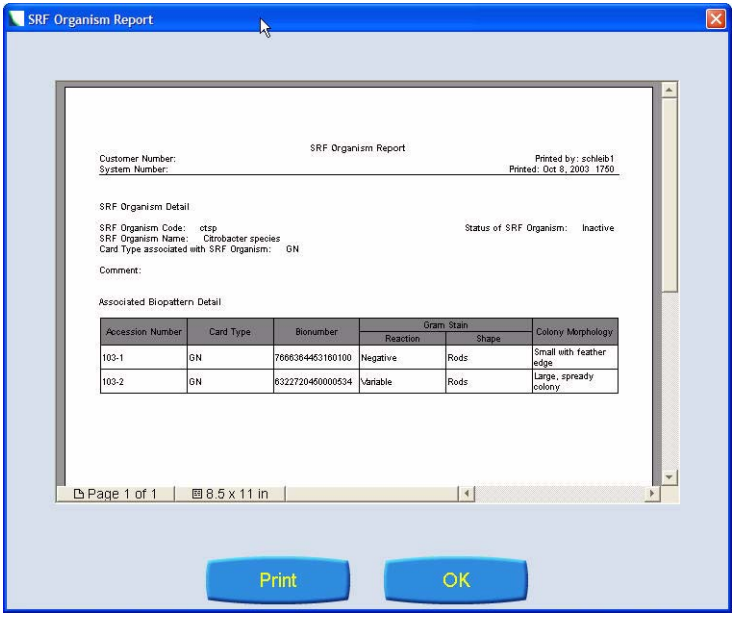

Figure 6-15: Example SRF Organism Report

MAINTAIN CUSTOMER QUALITY CONTROL 7

About This Chapter

This chapter describes maintaining customer Quality Control (QC).

Chapter Contents

Introduction to Working with QC Results • 7-2
Viewing QC Results • 7-2
Viewing Selected QC Results • 7-3
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Adding or Modifying QC Comments • 7-5
Changing the QC Reference ID • 7-5
Changing the Setup Technologist's Name • 7-5
Viewing QC Isolate Audit Records (Supervisor Only) • 7-5
Viewing Card Details • 7-6
Reviewing QC Results • 7-7
Approving QC Results (Supervisor Only) • 7-8
Applying Electronic Signature • 7-8
Creating and Viewing Batch Results • 7-9
Batch Review and Approve • 7-11
Recording Shipments • 7-11
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Introduction to Working with QC Results

All QC Isolates must be reviewed. Based on configuration, they may also need to be approved. If ID analysis returns a Low Discrimination result, the QC isolate is considered Qualified, and you will need to review the isolate and provide additional information to allow the isolate to become Final.

You can configure the following options:

- Review All Isolates
- Review and Approve All Isolates

You can set up the review process to allow for electronic signatures and batch selection.

Depending on your laboratory configuration settings, steps for reviewing and approving isolate results may flow differently. This chapter describes the settings individually.

For details about configuring your system software for reviewing results validation, see Chapter 9 Results Validation Configuration.

Viewing QC Results

QC Isolates appear in the navigation tree in the View QC Results window There are several conditions when you may need to provide the system software with additional information or perform a task before the results can become final. When an isolate is stopped for review or qualified, the icon beside the isolate represents the state of the test or isolate.

The following table describes the isolate states and icons that appear beside them in the navigation tree.

Table 7-1: Isolate Icons and Descriptions

Icon	Description
	All QC parameters are within range – Indicates that none of the QC isolates associated with this level contains a deviation.
	A QC parameter is out of range for one or more QC isolates – Indicates that one or more of the QC isolates associated with this level contains a deviation.
	Preliminary — Card is still processing, analysis not yet complete.

Table 7-1: Isolate Icons and Descriptions

Icon	Description
	Final, Qualified — Analysis is complete but the isolate needs additional information to become complete.
	Final, Not Qualified (Complete) — Analysis is complete, no additional QC isolate information or review is needed.
	To be Reviewed — Isolate needs review to leave this state. All isolates need to be reviewed.
	To be Approved — Isolate result needs to be approved to leave this state. (This icon appears if configured for approval.)

Viewing Selected QC Results

1) From View QC Results view, you can filter the isolates that appear in the navigation tree.

2) Select from the following **View By** options:

- QC Reference ID
- Card Type
- Date Tested

3) Select from the following **Filter By** options:

- Current, All Isolates
- Current, Deviation Only
- Current, To be Reviewed
- Current, To be Approved
- Custom (For details, see Creating a Custom Filter to View Cumulative QC Information on page 7-4.)

4) Once you have selected how you would like to view the QC Results, select a specific QC Result.

5) The selected result information appears in the active workspace.

Creating a Custom Filter to View Cumulative QC Information

Filter QC Results using your own filter criteria.

1) From the View QC Results view, select a **View By** option from the navigation tree.

2) From the **Filter By** drop-down list above the navigation tree, select **Custom**.

3) The Cumulative QC Search Criteria window appears.

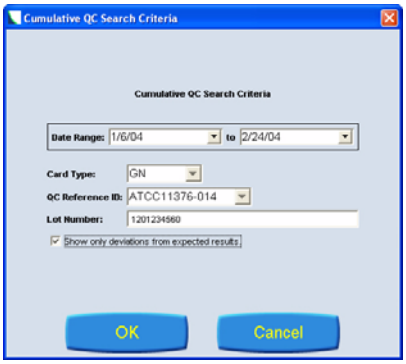


Figure 7-1: Cumulative Custom Filter

4) Select from the following options to view the desired QC Results:

- Select the **Date Range**.
- Select the **Card Type** from the drop-down list.
- Select the **QC Reference ID** from the drop-down list.
- Type in a *lot number* if you want to view results from a specific Lot Number.
- Select the check box to **Show only deviations from expected results**.

5) Click **OK**.

6) QC Isolates that meet the search criteria appear in the navigation tree.

7) The filter criteria for the search that you performed appear at the top of the workspace area.

Note: *The actual MIC range result, QC Isolate Group, and Card Type are flagged if different from expected.*

Adding or Modifying QC Comments

1) Select the QC isolate you want to update.
2) Make the changes in the **QC Comments** field on a selected test.
3) The system software updates the QC Isolate Group in the QC active workspace and adds the comment to the test. If the isolate is in the QC Cumulative workspace and you add a comment, then the QC test in the cumulative workspace is updated. A QC isolate is added to Cumulative after it is complete (for example, Reviewed or Reviewed/Approved).

Changing the QC Reference ID

To change the QC Reference ID:

1) From View QC Results view, select the card that you want to change.
2) Select the new QC Reference ID.
3) The system software updates the expected organism name and performs the required analysis based on the selected card type.

Changing the Setup Technologist's Name

If 21 CFR 11 Compliance Mode is not enabled, you can change the **Setup Technologist** name that appears in the field. For information on enabling 21 CFR 11 Compliance mode, see Chapter 10 General Configuration.

Select a name from the list in the **Setup Technologist** field. The system software is updated to reflect the change.

Note: *If 21 CFR 11 Compliance Mode is enabled, you cannot change the name of the Setup Technologist. The Setup Technologist is the user logged into the system software when the cassette is loaded into the instrument.*

Viewing QC Isolate Audit Records (Supervisor Only)

When you elect to view audit records for a QC isolate, the life cycle of the isolate appears in the window. This displays all recorded user changes. To view an isolate audit record:

1) From the View QC Results view, select an isolate from the navigation tree.
2) Click the **View Isolate Audit Records** icon in the right view bar.
3) The **Isolate Audit Report** appears.

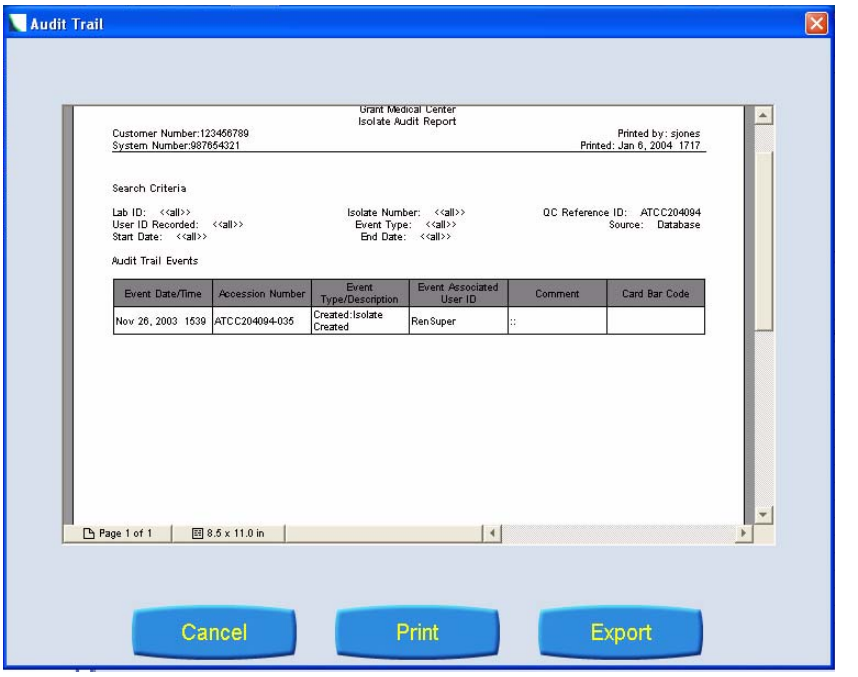


Figure 7-2: QC Audit Report Preview

4) Click **Print** to print a copy of the audit report.

5) Click **Export** to export the QC audit report to a CD. Make sure a CD is inserted.

Viewing Card Details

From QC Results, you can view the card details for individual AST and ID cards by clicking the **Card Details** icon in the right view bar. The detailed card information appears in the active workspace.

Figure 7-3: Card Details Icon

To print a report of the detailed card information, click the **Print** icon.

Reviewing QC Results

Based on your laboratory policy, you may need to review current QC results for both ID and AST cards and mark them as **Reviewed**. Depending on the results configuration, you may need to review and/or approve QC Results and apply your electronic signature (if electronic signature is enabled) to mark them **Reviewed**.

Note: *Depending on your review validation configuration, multiple reviews and approvals may be permitted without the user making any changes to the isolate information.*

QC results waiting to be reviewed are preceded by the **To be Reviewed** icon.

To review QC results, isolate group analysis must be complete.

To review QC Results:

1) Select a QC Isolate group preceded by the **To be Reviewed** icon.

2) Click the **Review Results** icon.

Figure 7-4: Review Results Icon

3) Depending on your results validation configuration, the following may occur:

If system software is configured based on the default setting, Review Critical Isolates:

- The system software flags the QC isolate as **Reviewed**. The **QC Isolate** icon changes to green.
- The system software transfers the QC isolate into the QC cumulative workspace for long-term storage.

If system software is configured for Review and Approve:

- The system software flags the isolate as **To Be Approved**. The **QC Isolate** icon changes to the **To Be Approved** icon.

4) If an Electronic Signature is needed, you are prompted to enter your *User ID* and *Password* to review or approve the results.

Note: *You can also Batch Review and Approve QC isolates. For details see* *Batch Review and Approve on page 7-11*.

Approving QC Results (Supervisor Only)

A supervisor can approve QC Isolate results. Multiple approvals are allowed without requiring a change to the information in the results. If the system software is configured for Batch review, you can approve one or more QC isolate groups at a time.

Note: *Any QC isolate with analysis complete and a status of **Final** is available for review and approval.*

QC results waiting to be approved are preceded by the **To be Approved** icon.

To approve QC Results:

1) Select a QC Isolate group preceded by the **To be Approved** icon.

2) Click the **Approve Results** icon.

Figure 7-5: Approve Results Icon

3) Depending on your results validation configuration, the following may occur:

- If Electronic Signature is required, you must enter your *User ID* and *Password* to approve these results.
- If an Electronic Signature is not needed, the final results are transferred to the QC Cumulative workspace for long-term storage.

Applying Electronic Signature

An electronic signature is a computer data compilation of a symbol or series of symbols authorized by an individual to be a legally binding equivalent to the individual's handwritten signature. In this case, the system software uses *User ID* and *Password* authentication to electronically sign results once they are Reviewed or Approved.

Applying an electronic signature is the equivalent of entering your *User ID* and *Password*. Depending on your system software configuration setting, one or more isolate groups can be selected to be signed electronically.

To electronically sign results:

1) Select the isolate or isolate groups to sign.

2) The system software prompts you to enter your *User ID* and *Password*.

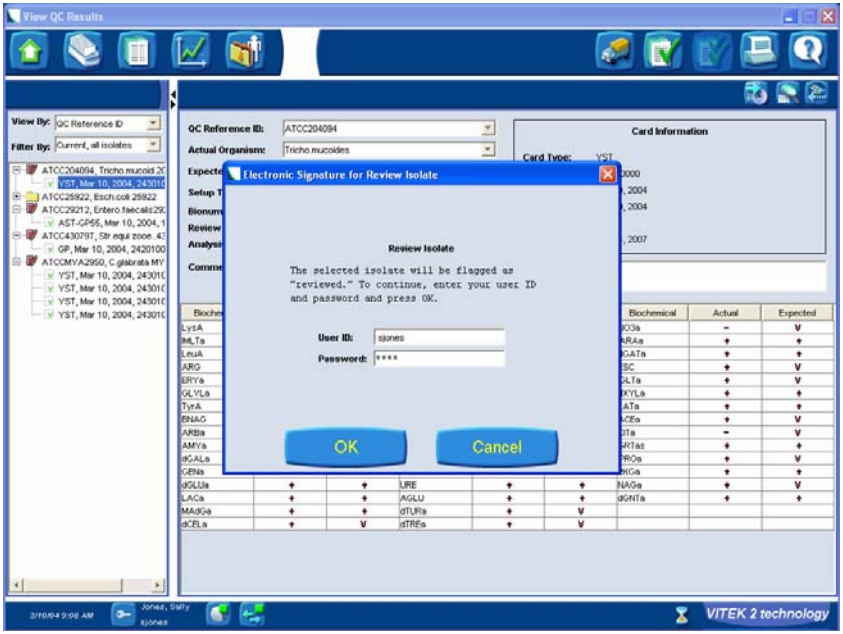


Figure 7-6: Review Confirmation Window

3) The *User Name* and *Password* is authenticated and the system software applies the electronic signature to selected test cards.

4) If you need to sign a subsequent set of tests during the same user session, the system software prompts you to enter your *password* each time.

Note: *If the User ID is not valid, the electronic signature is not applied due to authentication failure. If the user does not have authority to electronically sign, a message appears describing the issue. If the user signature fails repeatedly, the system software logs the user out of the session.*

Creating and Viewing Batch Results

Multiple isolate results are known as batch or cumulative results. Create batches of results to review and approve more than one QC isolate result at a time.

To create batches of isolate results:

1) Select the results that you want to view by clicking on the result and holding down the **Shift** key to select multiple results in a row or hold down the **Ctrl** key to individually click different isolate group results not listed in a particular order.

2) As you make your selections, the isolate groups appear in the active workspace.

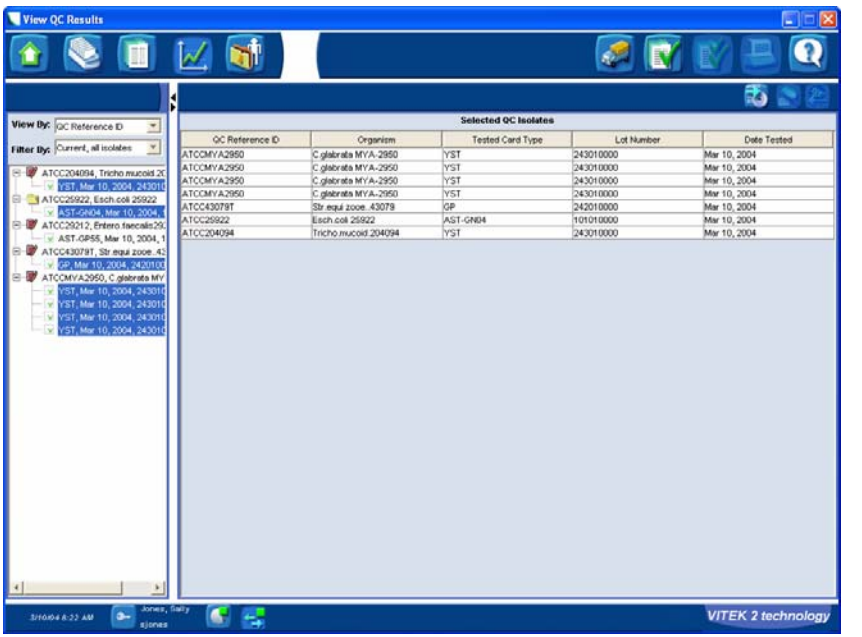

View QC Results
View By:
QC Reference ID
Filter By:
Current, all isolates
Selected QC Isolates
QC Reference ID
Organism
Tested Card Type
Lot Number
Date Tested
ATCCMYA2950 C.glabrata MYA-2950 YST 243010000 Mar 10, 2004
ATCCMYA2950 C.glabrata MYA-2950 YST 243010000 Mar 10, 2004
ATCCMYA2950 C.glabrata MYA-2950 YST 243010000 Mar 10, 2004
ATCCMYA2950 C.glabrata MYA-2950 YST 243010000 Mar 10, 2004
ATCC43079T Str.equi zoce..43079 GP 242010000 Mar 10, 2004
ATCC25922 Esch.coli 25922 AST-GN04 101010000 Mar 10, 2004
ATCC204094 Tricho.mucoid.204094 YST 243010000 Mar 10, 2004
VITEK 2 technology

Figure 7-7: Isolate Groups View

3) The following information displays:

- QC Reference ID
- Organism
- Tested Card Type
- Lot Number
- Date Tested

4) The list of selected isolates displays in the active workspace.

- If the status of all of the selected results is **To Be Reviewed**, you can perform a batch review at this point. Click **Review**.

- If the status of all of the selected results is **To Be Approved**, you can perform a batch approve by clicking **Approve**.

Batch Review and Approve

If **Batch Review** is enabled in the system software configuration settings, you can review batches of more than one isolate at the same time.

1) Create a batch of isolate groups to identify as **Reviewed**.

2) Click **Review**.

3) Confirm whether or not you want to flag all of these isolates as **Reviewed**.

4) Confirm whether you want to print QC Lab Reports.

5) Depending on your results validation configuration, the following may occur:

If system software is configured based on the default settings, **Review All Isolates**:

- The system software flags the QC isolates as **Reviewed**. The **QC Isolate** icon changes to green.
- The system software transfers the QC isolates into the QC cumulative workspace for long-term storage.

If system software is configured for **Review and Approve**:

- The system software flags the isolate as **To Be Approved**. the **QC Isolate** icon changes to the **To Be Approved** icon.

6) If an Electronic Signature is needed, you are prompted to enter your *User ID* and *Password* to review or approve the results.

Note: *The user who reviews the results cannot be the same user who approves the results.*

7) The isolate groups are flagged as **Reviewed**.

Recording Shipments

Approximately once or twice a month, you may need to record a shipment of new ID or AST cards. You can record a shipment using the system software.

A shipment can consist of more than one card type and can contain cards from more than one lot (production run). Cards from a specific lot may be sent in one or multiple shipments.

The individual boxes of cards contain cards of one card type only, all from the same lot. Each box has a bar code imprinted on it which contains the lot number, lot expiration date, and card type. A box can have more than one bar code imprinted on the box.

To record a shipment of cards, you must enter the following information into the system software:

- Lot number
- Date of receipt
- Quantity of boxes in the shipment (optional)

To add the QC shipment information to the system software:

1) From the View QC Results view, click the **Record Shipment** icon.

Figure 7-8: Record Shipment Icon

2) The Record Shipments window appears.

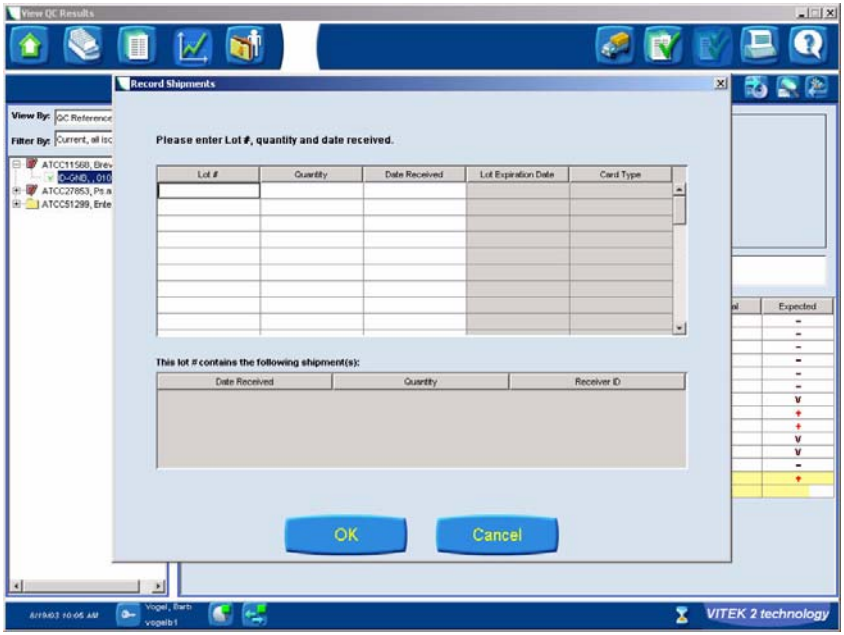


Figure 7-9: Record Shipment Window

3) Enter the lot number by manually entering or scanning the bar code number located on the box.

Note: *If the shipment information already exists in the software, if there is a problem with the bar code, or if the ID or AST card type is not known, the system software does not allow you to proceed.*

Note: *If a previous shipment was received, the information displays in the bottom of the window.*

4) Enter the *Quantity Received*.

5) Select the *Date Shipment was Received.*

Note: *If you change the date received, you will create a new shipment. If you enter the same received lot, you will update the shipment.*

6) If the appropriate information was entered, click **OK** to record the new card information.

7) The system software updates customer QC inventory with new shipment information.

Printing QC Laboratory Reports

There are several types of QC laboratory reports that can be generated:

- QC Laboratory Report for (ID, AST)
- QC Detailed Card Report
- Cumulative QC Reports

To print a QC report:

1) From the View QC Results view, click the **Print** icon.

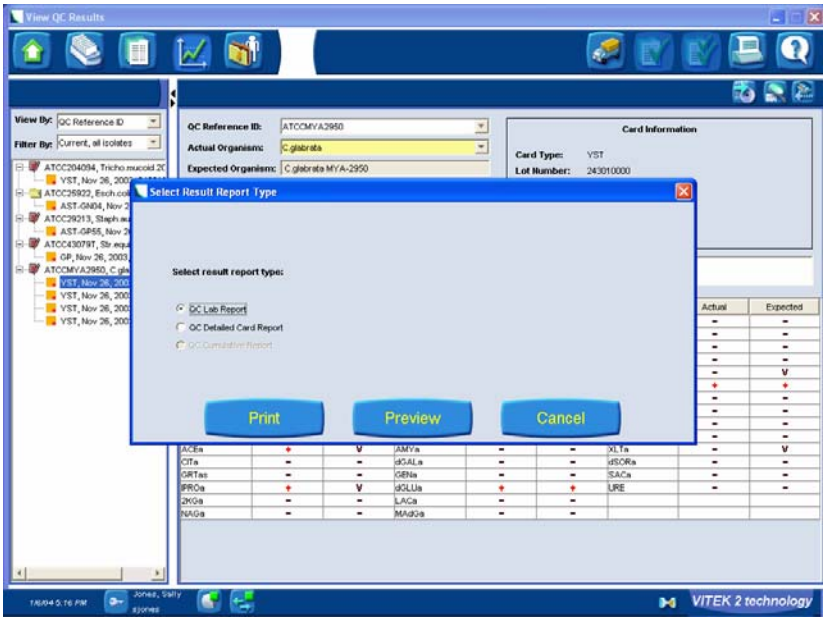


Figure 7-10: Select a Result Report Type

2) Select a Result Report type from the following:

- QC Laboratory Report
- QC Detailed Card Report
- QC Cumulative Reports (Only Available if a QC filter has been applied)

3) Click **Print**, **Preview**, or **Cancel**.

When you select an isolate and choose the Print option, the event is captured in the Isolate Audit Trail report. The Date/Time Printed field for the report also updates each time an isolate level report is selected and printed.

Note: *If a card under an isolate is selected and printed, neither the Isolate Audit Trail report nor the Date/Time Printed field for the selected report update to reflect the event.*

QC Laboratory Report

The QC Laboratory report prints the QC card results.

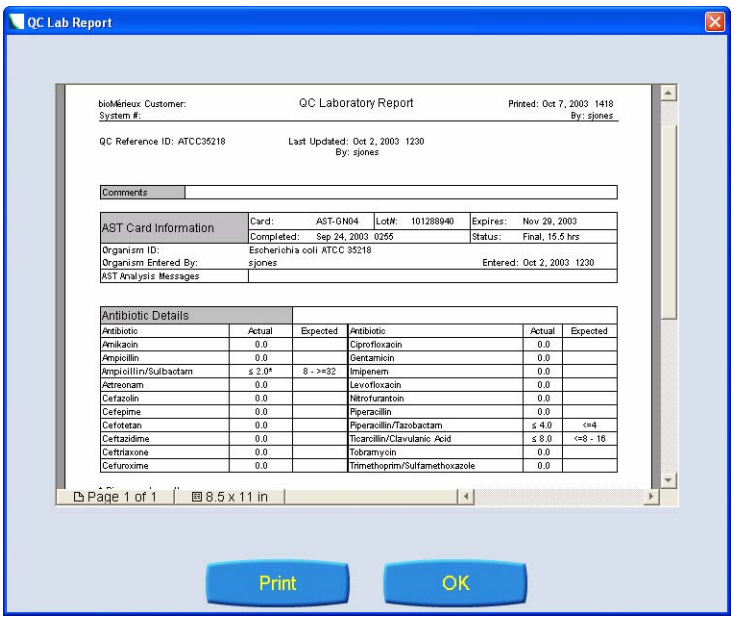
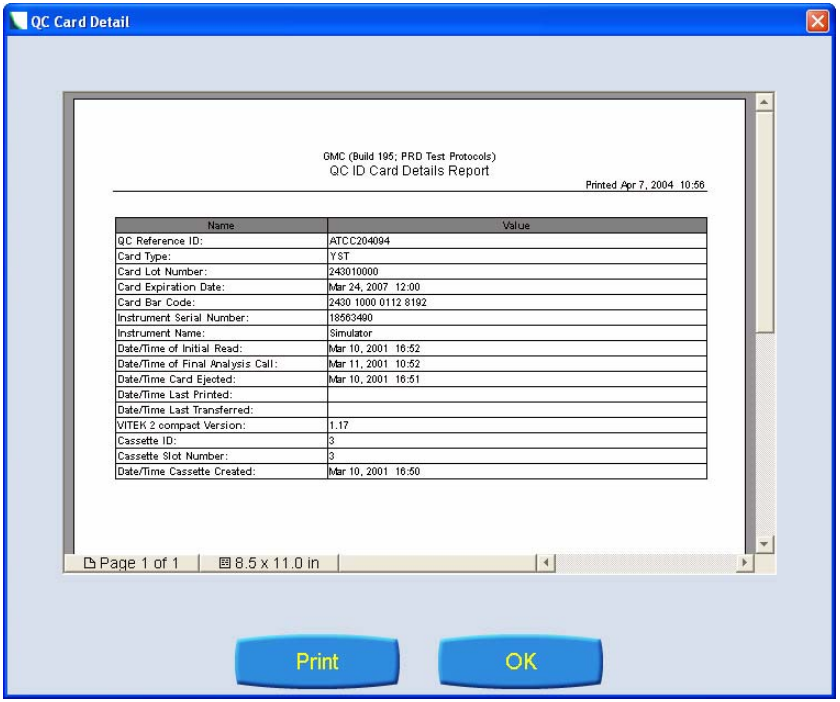

QC Lab Report
bioMérieux Customer:
System #:
QC Laboratory Report
Printed: Oct 7, 2003 1418
By: sjones
QC Reference ID: ATCC35218
Last Updated: Oct 2, 2003 1230
By: sjones
Comments
AST Card Information
Card: AST-GN04
Lot#: 101288940
Expires: Nov 29, 2003
Completed: Sep 24, 2003 0255
Status: Final, 15.5 hrs
Organism ID: Escherichia coli ATCC 35218
Organism Entered By: sjones
Entered: Oct 2, 2003 1230
AST Analysis Messages
Antibiotic Details
Antibiotic | Actual | Expected | Antibiotic | Actual | Expected
Amikacin | 0.0 | | Ciprofloxacin | 0.0 |
Ampicillin | 0.0 | | Gentamicin | 0.0 |
Ampicillin/Sulbactam | ≤ 2.0* | 8 - >=32 | Imipenem | 0.0 |
Aztreonam | 0.0 | | Levofloxacin | 0.0 |
Cefazolin | 0.0 | | Nitrofurantoin | 0.0 |
Cefepime | 0.0 | | Piperacillin | 0.0 |
Cefotetan | 0.0 | | Piperacillin/Tazobactam | ≤ 4.0 | <=4
Ceftazidime | 0.0 | | Ticarcillin/Clavulanic Acid | ≤ 8.0 | <=8 - 16
Ceftriaxone | 0.0 | | Tobramycin | 0.0 |
Cefuroxime | 0.0 | | Trimethoprim/Sulfamethoxazole | 0.0 |
Page 1 of 1
8.5 x 11 in
Print
OK

Figure 7-11: QC Laboratory Report

QC Detailed Card Report

The QC Detailed Card report prints details about the QC card processing.



Name	Value
QC Reference ID:	ATCC204094
Card Type:	YST
Card Lot Number:	243010000
Card Expiration Date:	Mar 24, 2007 12:00
Card Bar Code:	2430 1000 0112 8192
Instrument Serial Number:	18563490
Instrument Name:	Simulator
Date/Time of Initial Read:	Mar 10, 2001 16:52
Date/Time of Final Analysis Call:	Mar 11, 2001 10:52
Date/Time Card Ejected:	Mar 10, 2001 16:51
Date/Time Last Printed:	
Date/Time Last Transferred:	
VITEK 2 compact Version:	1.17
Cassette ID:	3
Cassette Slot Number:	3
Date/Time Cassette Created:	Mar 10, 2001 16:50

Figure 7-12: QC Detailed Card Report

QC Cumulative Report

This report consolidates QC results and sorts them by testing date and lot number into a single cumulative report. This allows you to easily compare the test results for one or more card lot numbers.

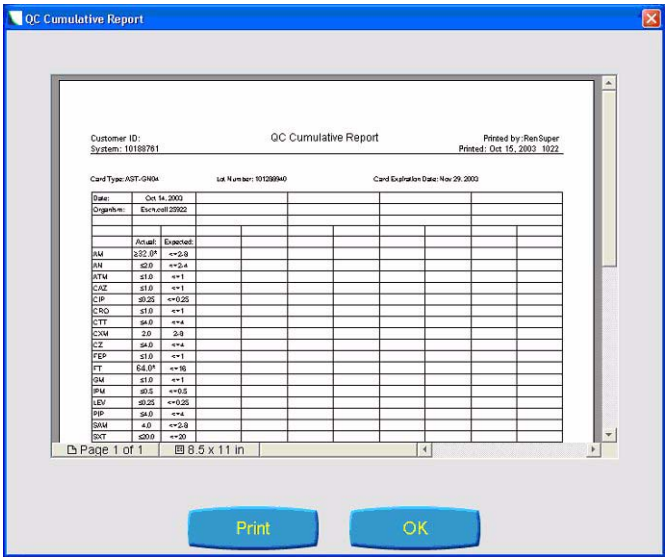
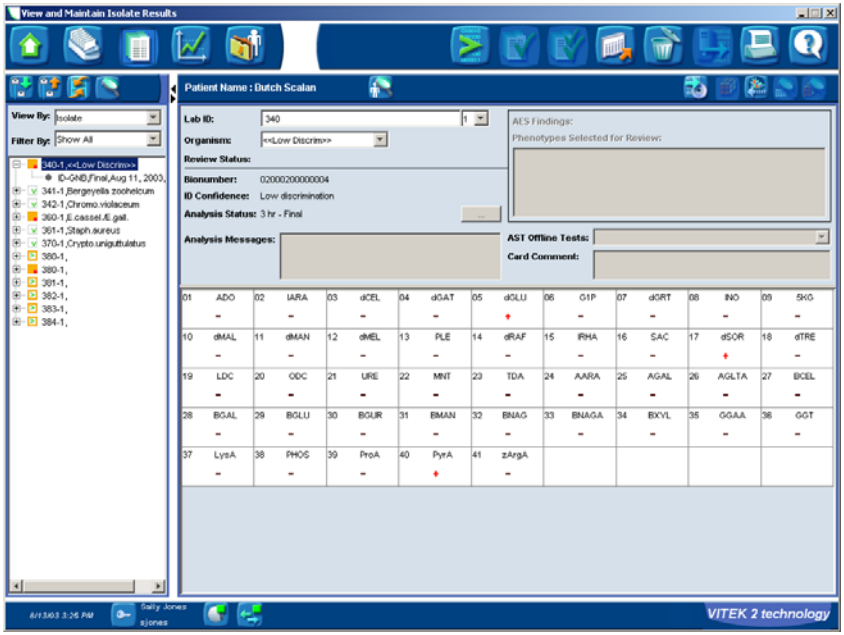


Figure 7-13: QC Cumulative Report

Part III: View and Maintain Results


View and Maintain Isolate Results
Patient Name : Dutch Scalan
View By: Isolate
Filter By: Show All
340-1,<<Low Discrim>>
ID-GNB,Final,Aug 11, 2003,
341-1,Bergeyella zoohelcum
342-1,Chromo.violaceum
360-1,E.casseliflE.gall.
361-1,Staph.aureus
370-1,Crypto.uniguttulatus
380-1,
380-1,
381-1,
382-1,
383-1,
384-1,
Lab ID: 340
Organism: <<Low Discrim>>
Review Status:
Bionumber: 02000200000004
ID Confidence: Low discrimination
Analysis Status: 3 hr - Final
Analysis Messages:
AES Findings:
Phenotypes Selected for Review:
AST Offline Tests:
Card Comment:
01 ADO - 02 IARA - 03 dCEL - 04 dGAT - 05 dGLU + 06 G1P - 07 dORT - 08 INO - 09 5KG -
10 dMAL - 11 dMAN - 12 dMEL - 13 PLE - 14 dRAF - 15 IRHA - 16 SAC - 17 dSOR + 18 dTRE -
19 LDC - 20 ODC - 21 URE - 22 MNT - 23 TDA - 24 AARA - 25 AGAL - 26 AGLTA - 27 BCEL -
28 BGAL - 29 BGLU - 30 BGUR - 31 BMAN - 32 BNAG - 33 BNAGA - 34 BXYL - 35 GGAA - 36 GGT -
37 LysA - 38 PHOS - 39 ProA - 40 PyrA + 41 zArgA -
Sally Jones
sjones
VITEK 2 technology

VIEW AND MAINTAIN ISOLATE RESULTS 8

About This Chapter

This chapter describes viewing, maintaining, reviewing, and approving any information associated with isolate results.

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Access the Isolate Results View

From the View and Maintain Isolate Results view, you can browse through the isolate results. The isolate results are available in the navigation tree in a navigation tree structure. The results are organized by isolate groups.

You can easily browse through the isolate results using the left view buttons to select the order of appearance for isolate groups in the navigation tree.

To access this view:

1) From the Main view, click **Enter Isolate View**.

Figure 8-1: Enter Isolate View Icon

2) The View and Maintain Isolate Results view appears.

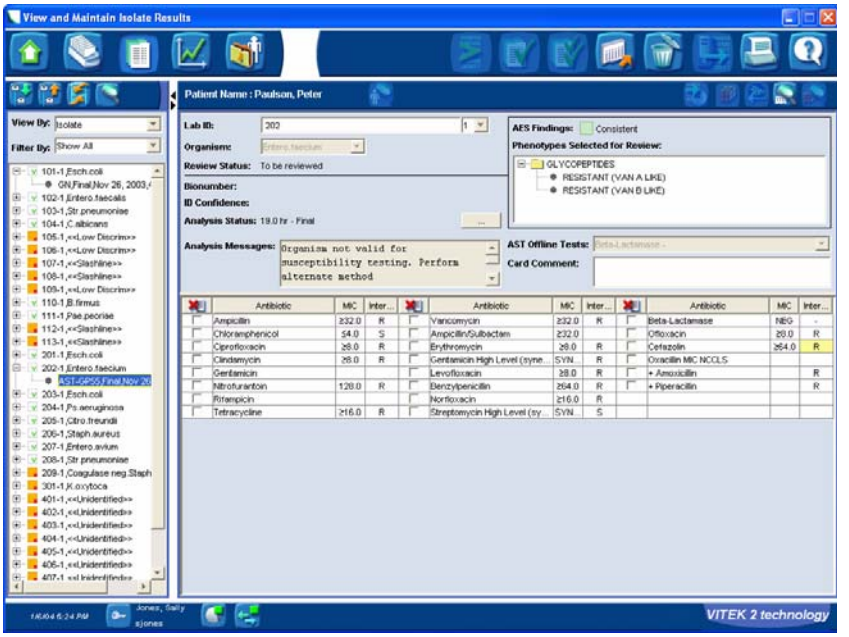

Figure 8-2: Isolate Results View

Using the Navigation Tree to View Specific Isolate Results

To view isolate results, use the left view bar and navigation tree to select the order of appearance for the isolate groups in the navigation tree.

1) From the View and Maintain Isolate Results view, select the order of the results displayed by selecting one of the following categories available in the **View By** drop-down list:

- Isolate
- Tech
- Bench (Clinical Only, if enabled in configuration)
- Patient (Clinical Only, if enabled in configuration)

2) You can also filter the results by status. The following status filters are available in the **Filter By** drop-down list:
   - Preliminary (Default)
   - Show All
   - Qualified
   - To be Reviewed (if enabled in configuration)
   - To be Approved (if enabled in configuration)
3) When viewing by isolate, choose an *isolate group* or an individual *test card* from the navigation tree. Based on your selection, different functionality is available.
4) The information for the selected item appears in the active workspace.
5) Make any necessary modifications. For details, see Modifying Isolate Groups and Test Cards on page 8-11.

Active Workspace versus Inactive Workspace

The information that appears in the navigation tree is retrieved from the active workspace. This information can be edited. The length of time that the isolate remains in the active workspace is controlled by user configuration. For configuration details, see Chapter 10 General Configuration.

Isolates that can no longer be edited are in the inactive workspace. The inactive workspace acts as a repository for laboratory reports and QC laboratory reports. The inactive workspace is maintained by user configuration.

Expanding and Collapsing the Navigation Tree

When using the navigation tree, to expand or collapse an individual item click the (+) or (–) or click one of the icons in the left view bar:

1 — Expand All

2 — Collapse All

3 — Refresh

4 — Search Accession Number

5 — Isolate Level

6 — Card Level

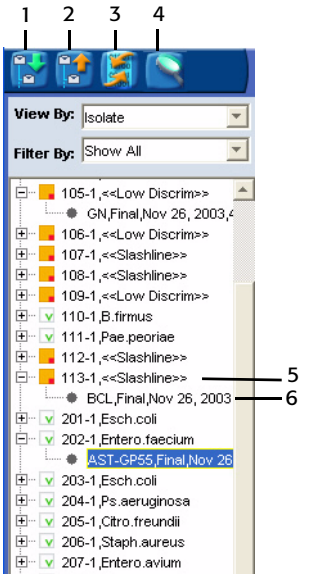

Figure 8-3: Navigation Tree

Search by Accession Number

When viewing the navigation tree, you can search isolate results by selecting the **Search Accession Number** icon.

1) From the View and Maintain Isolate Results view, select the **Search Accession Number** icon.

Figure 8-4: Search Accession Number Icon

2) From the Accession Number window, enter an **Accession Number**.

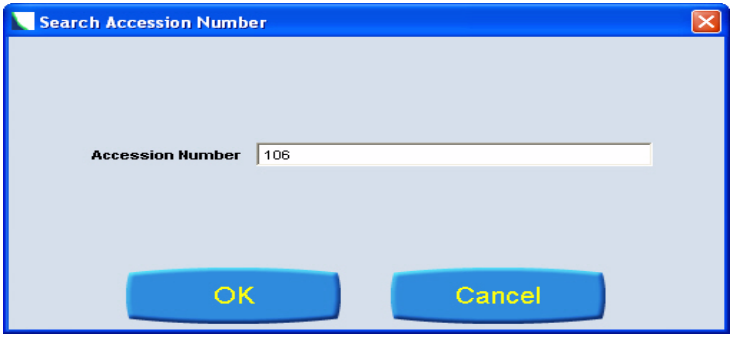

Figure 8-5: Search Accession Number Window

3) Click **OK** to complete the search.

The system will search for the Accession Number within the navigation tree and will display the results.

Status Icons and Descriptions

Isolates appear in the navigation tree of the View and Maintain Isolate Results view. Based on the configuration settings for your laboratory you may need to provide the system software with additional information before the results can become final. The icon beside a result represents its status.

The following table describes the status of the results and defines the icons that appear beside the results in the navigation tree.

Table 8-1: Status Icons and Descriptions

Icon	Description
	Preliminary — Isolate is still receiving raw data readings from the instrument; isolate is not final.
	Final, Qualified — Isolate final with missing information. Examples of missing information include: • <<low discrimination>> • <<slashline>> • Beta lactamase (when configured for CLSI™) • Patient information • Missing Organism
	Isolate Complete — Sent to Lab Information System (LIS) • Isolate final • Isolate is not qualified • Isolate does not need review • Isolate does not need approval • If enabled, isolate sent to LIS • Isolate is a candidate to be removed from the active workspace
	To be Reviewed — Isolate final and needs to be reviewed (click the **Review** icon) Based on user configuration of Results Validation • All isolates • Critical isolates only
	To be Approved — Isolate is final and needs to be approved (click the **Approve** icon) Based on user configuration of Results Validation • All isolates • Critical isolates only

Qualified Isolates

After the system software has analyzed the test card readings, isolates with the following characteristics will be flagged as qualified.

Table 8-2: Qualified Isolates

Type	Description
ID Analysis Problems	• Slashline results for an organism without an auto-resolution configured. • Low discrimination results
AST Analysis Problems	• Offline test required for an AST card to complete analysis. Analysis must be complete and the isolate group must contain an organism that requires an offline test for antibiotic interpretation.
Validation Analysis Problems	• Detection of user configured phenotype.
Patient demographics problems	• If enabled • Laboratory Identification number that is not linked to a patient.

Using the Right View Bar to View Specific Results

When viewing an isolate result, you can view additional detailed information or perform a task by clicking one of the buttons on the right view bar.

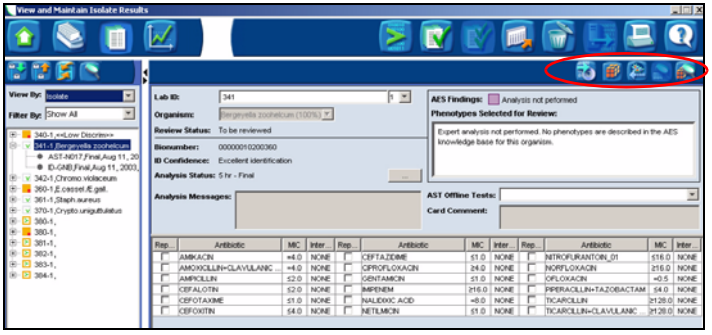

Figure 8-6: Right View Bar

Depending on the selected item in the navigation tree and the system software configuration parameters, the following view options become available:

- **Export Isolate and Raw Instrument Data** — Exporting isolate and Raw instrument data allows you to copy data to a CD. This helps bioMérieux Customer Support troubleshoot ID analysis or AST analysis problems.
- **View AES Graphic (Clinical Use)** — When viewing isolates, if the isolate has been expertized you can click the **View AES Graphic** icon to see a graphical representation of MIC distributions, phenotypes, and observed MIC results. For more information, see Viewing AES Graphic (Clinical Use) on page 8-25.
- **View Detailed AES Report (Clinical Use)** — When viewing results, if the results have been expertized you can click **View Detailed AES Report** to see expertization details. For details on AES, see Viewing Detailed AES Report (Clinical Use) on page 8-24.
- **View Audit History** — When working with isolates, you can view the audit history of an isolate to see the life cycle of an isolate from creation to archive. The audit history also includes all user changes. For details, see Viewing an Isolate Audit Trail on page 8-29.
- **View Card Details** — When you select an individual card, whether it is an AST card or an ID card, you can click **View Card Details** to display the detailed card information. You can also print this information by clicking the **Print** icon. For details, see ID Card Details on page 8-18 or AST Card Details on page 8-19.
- **Send to SRF (Industrial Use)** — Depending on the criteria your laboratory uses to determine a SRF organism, when the criteria is met, you can send the result to SRF. For details, see Chapter 6 Criteria for Merging ID Results with SRF Results.

Note: *When 21 CFR 11 is enabled, you can also click the **View Previous Versions** icon to view previous versions of the lab report.*

Modifying Isolate Groups and Test Cards

When making changes from the View and Maintain Isolate Results view, make sure you are making changes at the appropriate level.

Isolate Group Level — When you need to make a change to an isolate group, select the isolate level in the navigation tree and make the necessary changes in the active workspace.

Card Level — When you need to make a change at the card level, select the actual card that you need to change and make the necessary changes in the active workspace.

For example:

> A laboratory technologist realizes that they added an AST card to the wrong isolate group. They need to make a change to the AST card and not to the entire isolate group. To do so, they select the individual AST card in the navigation tree to make the necessary changes to the AST card with information in the workspace area.

To modify all cards in an isolate group, select the isolate to make the necessary changes to the group.

When working with isolate groups at the isolate level or test card level from the navigation tree, you can view the following information at any time:

- Laboratory Identification Number
- Isolate Number
- Organism
- Patient/Specimen Information
- Review Status
- ID Confidence
- Analysis Status
- Analysis Messages
- AES Findings
- AST Offline Tests
- Test Results

- Additional Information
  - Organism Quantity
  - Bench

You can modify some of the isolate information and card level information. The ability to change some of these isolate result fields depends on your system configuration.

Changing the Laboratory Identification Number

To modify information associated with test results:

1) From View and Maintain Isolate Results, select an isolate group or an individual test card.

Note: *If 21 CFR 11 is enabled as a configuration parameter, any change made to an isolate group creates a new version of the isolate lab report and indicates a change has been made after final call.*

2) From the View and Maintain Isolate Results view, select the Laboratory Identification Number and make any necessary changes.

3) The system software displays a window requesting that you confirm the patient information is correct (if patient demographics is enabled in configuration.)

Note: *If the isolate is complete (shown by a green status icon), the user must enter a change comment.*

4) The system software updates the Laboratory Identification Number for all cards in the selected isolate group.

Changing the Isolate Number

If you need to change the isolate number for an isolate group or a particular card in an isolate group:

1) From the View and Maintain Isolate Results view, select an isolate group or an individual test card.

Note: *If 21 CFR 11 is enabled, any change made to an isolate group creates a new version of the isolate lab report and indicates a change has been made after final call.*

2) Select the isolate number and make any necessary changes.

3) The system software displays a confirmation window.

4) The system software updates the isolate number for the card or all cards in the selected isolate group.

Note: *If the isolate is complete (shown by a green status icon), the user must enter a change comment.*

Changing the Organism Name

An Isolate with an AST card can only be changed at the isolate level.

AST Card
–Isolate level changes only

An Isolate with only an ID card can be changed at either the Isolate level or the card level.

ID Card
–Isolate level changes
–Card level changes

To modify information associated with isolate results:

1) Select an isolate group or an individual test card.

Note: *If 21 CFR 11 is enabled, any change made to an isolate group creates a new version of the isolate lab report and indicates a change has been made after final call.*

2) Select the Organism Name and make any necessary changes.

- If the result is low discrimination or slashline, the candidate Organism Names appear in the drop-down list.
- If the identification results in low discrimination and you change the Organism Name, the normalized percent probability for low discrimination is replaced by the percent probability for the selected organism.
- If the Organism Identification returns a single organism or no organisms, you cannot change the Organism Identification.

3) The system software displays a window requesting that you confirm the changed information is correct.

4) The system software updates the Organism Name for all cards in the selected isolate group and performs the necessary re-analysis.

Viewing or Updating Patient/Specimen Information

If **Patient** or **Specimen Information** is enabled, you can update this at any time.

1) Select an Isolate group.

Note: *Changes cannot be made at the card level.*

2) Click **View Specimen Information** to make changes to the patient information.

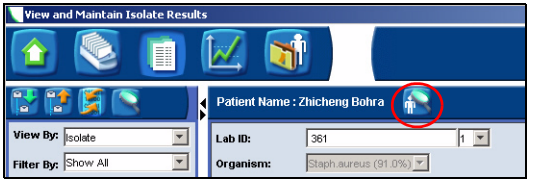

Figure 8-7: View Patient/Specimen Information Icon

3) The View Specimen Information window appears.

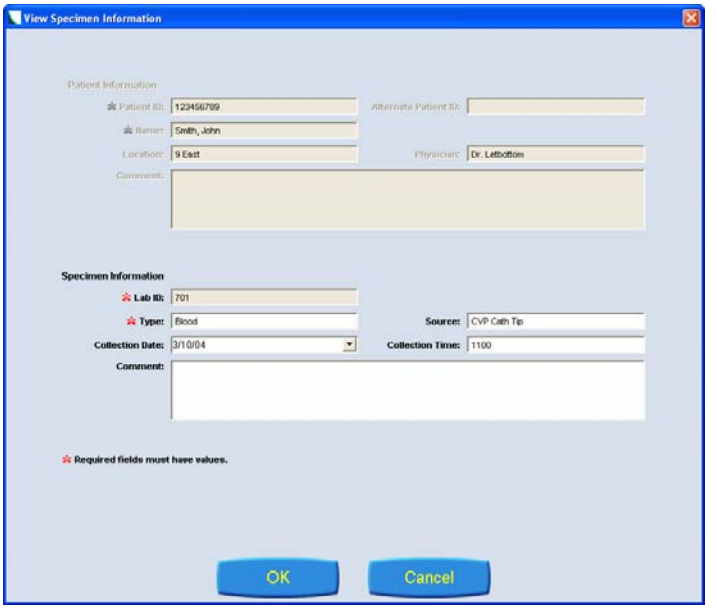

Figure 8-8: View Specimen Information Window

4) Make any necessary changes to the specimen information.

5) The system software confirms the changes and is updated to reflect the changes. For details, see Chapter 5 Manage Patient Information (Clinical Use).

Changing Additional Information and Organism Quantity

To modify information associated with isolate results, at the isolate level:

1) Select an isolate group or an individual test card.

Note: *If 21 CFR 11 is enabled, any change made to an isolate group creates a new version of the isolate lab report and indicates a change was made after final call.*

2) Select the button labeled **. . .** to view additional information.

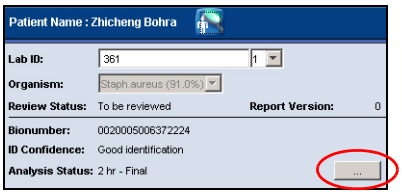

Figure 8-9: Additional Information Button

3) The Additional Isolate Information window appears.

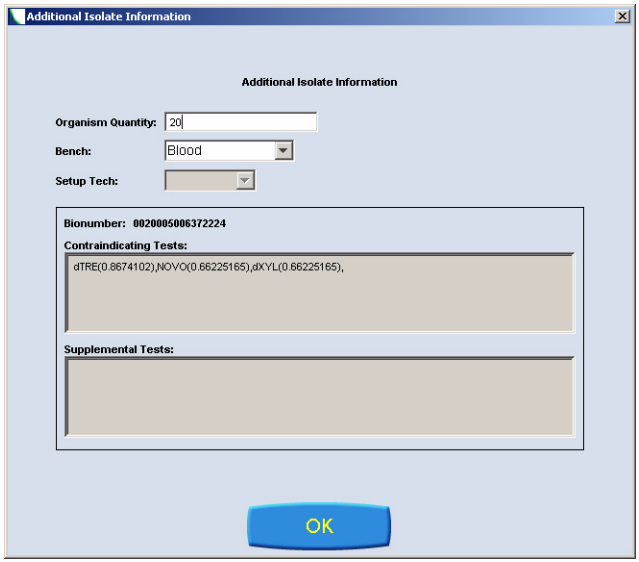

Figure 8-10: Additional Isolate Information Window

4) Enter or select a new **Organism Quantity** and make any necessary changes.

5) Enter or select a new **Bench Name** and make any necessary changes.

6) Enter or select a new **Setup Tech** and make any necessary changes.

Note: *If 21 CFR 11 is enabled, the Setup Technologist cannot be changed.*

7) The following information is read-only:

- Bionumber
- Contraindicating tests
- Supplemental tests

8) The system software updates the organism quantity for the card or all cards in the selected isolate group and performs the necessary re-analysis.

Confirm Changes to the Isolate Group

Depending on the **Result Validation** configuration, when making changes to the isolate information, you may be prompted to add change comments.

Depending on the state of the isolate, the Supervisor who made the change may be required to complete the approval process.

The following information defines when change comments and Supervisor approval are needed:

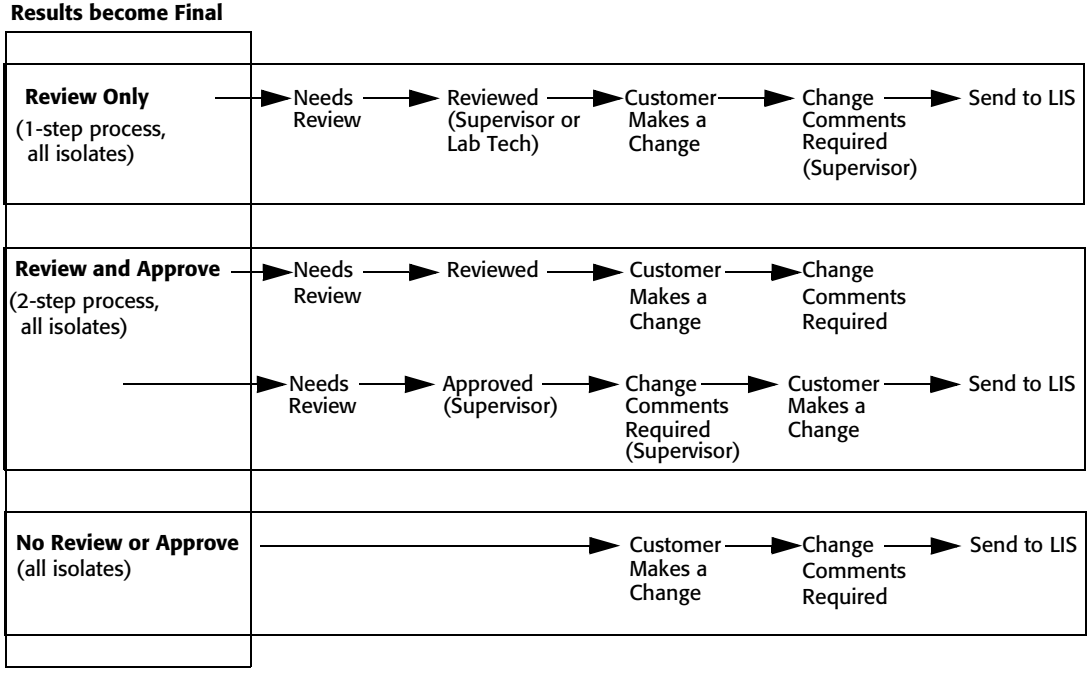

Figure 8-11: Result Validation Configurations

ID Card Details

View Detailed Biochemical Results

Note: *Card status must be final to view biochemical results. For details on the biochemical reactions, refer to the Online Product Information for a specific card type.*

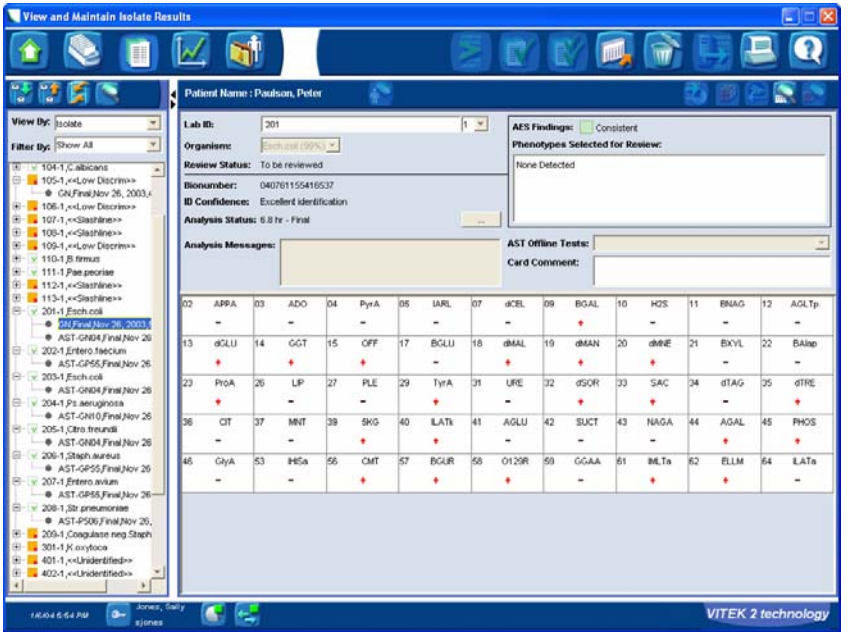

Figure 8-12: View ID Card Details

When you want to view isolate result details for a final identification test, you can select the individual card to view the details for the individual wells.

1) From the View and Maintain Isolate Results view, select an identification card by selecting either the card itself or an isolate group containing an identification card only.

2) The detailed identification information displays in the active workspace, sorted by well number for each tested biochemical.

The following biochemical results may appear in the result column for tests:

TABLE 8-3: BIOCHEMICAL RESULTS

+	Positive
–	Negative
(+)	Weak Positive
(–)	Weak Negative

AST Card Details

View Detailed Antibiotic Results

When viewing AST card results, the detailed antibiotic results appear in the active workspace.

1) Select an AST card or an isolate group containing one or more AST cards to view tested and deduced antibiotics.

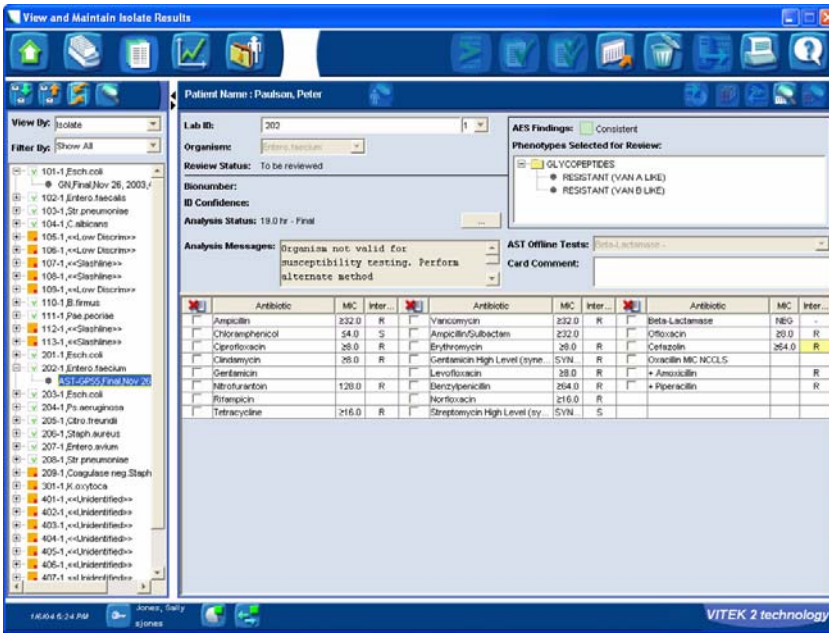

Figure 8-13: View AST Card Results

2) The following four sections appear in the detailed antibiotic results area of the active workspace.

- **Report —** When the check box beside the Antibiotic is not selected, the antibiotic appears on all reports. When the antibiotic is selected, the antibiotic does not appear on the Chart Report and is not sent to the LIS. For details see Report Selected Antibiotics on page 8-21.
- **Antibiotic —** Name of the antibiotic on the AST card.
- **MIC Value —** A routine susceptibility test value used to represent the minimum inhibitory concentration of antimicrobial agents. MIC values are measured in micrograms per milliliter (µg/mL).

The following may appear in the MIC column for tests (these cannot be changed):

TABLE 8-4: MIC VALUES

ESBL	POS or NEG
Beta lactamase	POS or NEG
Synergy	SYN-S or SYN-R
VRSA Screen	POS or NEG
Cefoxitin Screen	POS or NEG

- **Interpretation —** Expertization interpretation is based on the MIC Interpretation Guidelines. Use CTRL + click to change the MIC interpretation.

For an antibiotic the following are available interpretations:

TABLE 8-5: ANTIBIOTIC INTERPRETATIONS

S	Susceptible
I	Intermediate
R	Resistant

These interpretations are available for the following tests:

TABLE 8-6: TEST INTERPRETATIONS

ESBL	+ or –
Beta lactamase	+ or –
Oxacillin	S or R

TABLE 8-6: TEST INTERPRETATIONS

Synergy	S or R
VRSA Screen	+ or –
Cefoxitin Screen	+ or –

Unknown Observed Interpretation

In some instances, the VITEK® 2 Systems software may allow you to see an MIC for a tested antibiotic but not an interpretation on the lab report or in the Results view.

Reasons why an observed interpretation can be unknown (i.e., blank):

- No breakpoints are defined in the active parameter set MIC Guideline for the tested organism-antibiotic combination.
- Partial breakpoints defined (Unusual MIC) in the active parameter set MIC Guideline for the organism-antibiotic combination. In this case, the blank interpretation is highlighted and the system software explains the findings.
- For the tested organism-antibiotic combination, the MIC interpretation spans category ranges. For example, because of the breakpoints, an MIC of >=4 is interpreted as "I/R". In this case, the system software will not highlight the "blank" interpretation in Results view.

Report Selected Antibiotics

Selected antibiotics are displayed in the detailed antibiotic results table in the active workspace. This means only antibiotics without the report check box selected appear on the chart report, or are sent to an LIS.

1) From the View and Maintain Isolate Results view, select an AST card.

2) Select the check box beside the antibiotic that you do not wish to report.

3) The Chart report does not print antibiotics selected to be suppressed.

Antibiotics to Suppress

A result for an organism/antibiotic combination that may have a limitation listed in the package insert may be suppressed from reporting. To select antibiotics to suppress and antibiotics to deduce, see Chapter 9 Configuring AST Analysis.

Note: *If an organism-antibiotic combination is suppressed, AST analysis is complete, and AES analysis has been performed, the results appear in the active workspace and on the lab report. However, the results do not appear*

on the Chart Report, and results are not sent to the LIS. For more information, see Chapter 9 Configuring AST Analysis.

AES Findings (Clinical Use)

The Advanced Expert System™ (AES) is a software program for the validation and interpretation of VITEK® 2 Systems susceptibility results. When biologic validation is enabled, AES automatically checks susceptibility results as the VITEK® 2 System analysis program processes them. Susceptibility (AST) results are further analyzed using AES in an effort to validate the results and detect resistant phenotypes.

The AES findings appear on the View and Maintain Results view in the upper right corner.

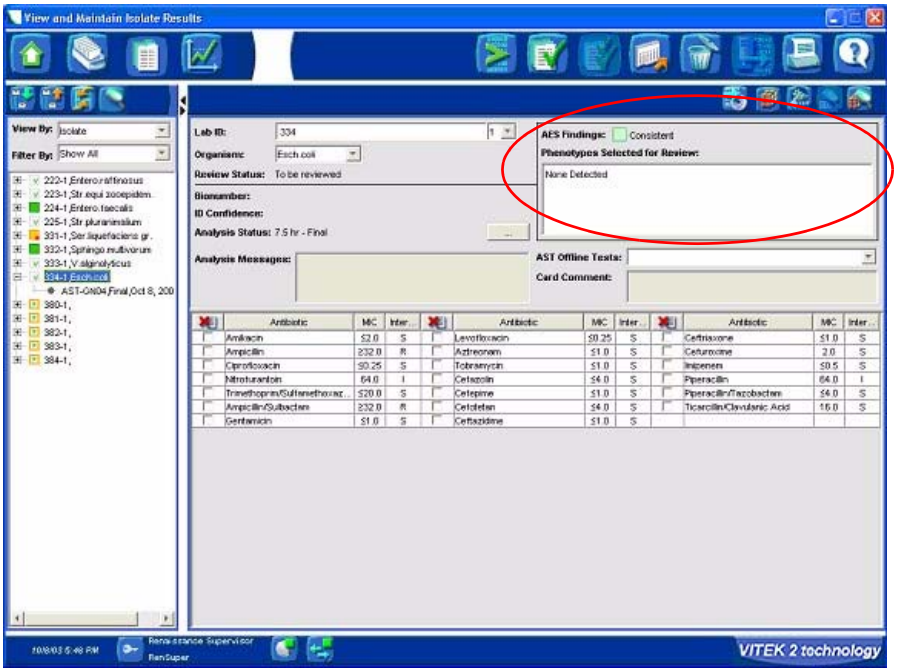

Figure 8-14: AES Findings

AES compares observed instrument MIC results and the organism identification to a knowledge base of expected MIC distributions. AES determines what phenotypes are being expressed by the organism.

If AES detects differences or inconsistencies, there may be a technical error (for example, a mixed culture) or the organism is more susceptible or resistant than the AES expected results. Thus, AES can recognize and inform the user about emerging resistance patterns.

The detailed AES Report and the AES Graphic can help you to determine and consider all of the possible options. For details see Viewing AES Graphic (Clinical Use) on page 8-25 or Viewing Detailed AES Report (Clinical Use) on page 8-24.

Possible AES Findings

After analysis is performed, the results are expertized based on the AES Configuration parameters set up for your laboratory. For details, see Chapter 11 Accessing AES Configuration.

The AES Findings are displayed in the upper right corner of the View and Maintain Results view. Phenotypes selected for review: The phenotypes detected by AES are displayed in the window if they are configured or selected to stop for review in the Result Validation Configuration. For details see Chapter 9 Results Validation Configuration.

AES provides the following levels of confidence in the response returned.

TABLE 8-7: AES CONFIDENCE LEVELS

Icon	Confidence Level	Description
Green	Consistent	One or more phenotypes detected with no changes to MIC values. Therapeutic Changes may also be detected.
Yellow	Consistent with Corrections	One or more phenotypes detected when including an MIC value change or a test value change in the AES analysis. The tested MIC value or test value is reported. Therapeutic changes may also be detected. **NOTE:** A correction to an MIC value or a correction to a test (i.e. beta lactamase, ESBL, etc.) will result in an AES confidence of **Consistent with Corrections.**
Red	Inconsistent	Phenotypes cannot be detected. Antibiogram is inconsistent with the AES knowledge base.

TABLE 8-7: AES CONFIDENCE LEVELS

Icon	Confidence Level	Description
Purple	Expert Analysis Not Performed	Phenotypes cannot be detected. Phenotypes for the detected organism are not described in the AES knowledge base.

Viewing Detailed AES Report (Clinical Use)

The Detailed AES report provides you with detailed information related to AES findings. All recognized phenotypes for the selected isolate are printed in this report.

Note: *The AES detailed report only includes the Recognized and Best phenotypic matches.*

1) From within the View and Maintain Isolate Results view, select an isolate group with an AST card.

2) Click **View Detailed AES Report**.

3) The **Detailed AES Report** is arranged in four sections: Phenotypes, Therapeutic Interpretations, MIC Differences, and Antibiotic Deductions:

- Phenotypes

  Antibiotic Family – Lists each tested antibiotic family.

  Detected Phenotypes – Lists one or more phenotypes proposed by AES for each antibiotic family.

- Therapeutic Interpretations

  Antibiotic – Lists antibiotics with Therapeutic Changes.

  Interpretation Changes – Defines the change.

  Reason (rule or phenotype) – Reasons may include: an MIC change, a Forced Resistant Rule, or the detection of a resistant phenotype. When more than one phenotype is detected, the most resistant change is used.

- MIC/Test Differences – AES can propose up to 10 two-fold dilution changes (increase or decrease) to the MIC to match a phenotype(s). The actual MIC is not changed on the Laboratory Results. A test change means that a test can be modified. A test correction is equal to 10 MIC dilutions.

  Antibiotic Family – Lists each tested antibiotic family

  Antibiotic(s)/Test – Lists the antibiotic tested.

Detected Phenotypes – Lists one or more phenotypes proposed by AES for each antibiotic family.

Description of Findings – Explains why AES proposed a change to the MIC.

- Antibiotic Deductions – Explains why the antibiotic was deduced either because of Antibiotic equivalency or the detection of a phenotype.

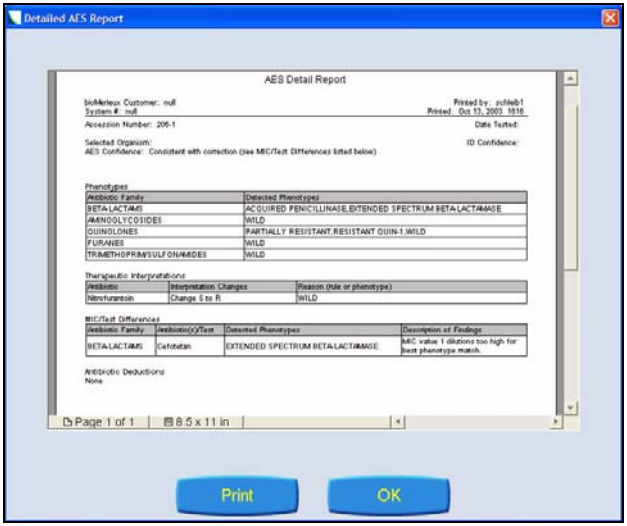

Figure 8-15: Detailed AES Report

4) Click **Print** to print the report to the workstation printer.

Viewing AES Graphic (Clinical Use)

The purpose of the AES Graphic is to show by phenotype the expected AES MIC distributions in the AES database superimposed with the observed values for selected isolates.

AES uses a ranking system to determine the confidence of the phenotypic match detected. The following rankings are displayed in the AES Graphic:

★ Possible phenotype – One star represents a good match.

★★ Recognized phenotype – Two stars represents a better match.

★★★ Best phenotype – Three stars represents the best match.

Viewing MIC Distributions

To view the MIC distributions for phenotypes corresponding to susceptibility test results:

1) From within the View and Maintain Isolate Results view, select an isolate group containing an AST card.

2) Click **View AES Graphic**.

Note: *The AES Graphic displays only the tested antibiotic results.*

3) The AES graphic appears in the active workspace providing a visual graph depicting the antibiograms.

4) Move the mouse over the greater than, less than, or equal to indicators to see popup containing the observed MIC value. The shape of the indicator gives you a graphical representation of the MIC distribution values.

Greater than – Observed MIC is greater than the highest value tested.

Less than – MIC was lower than the lowest value tested.

Equal to – MIC is equal to the value observed.

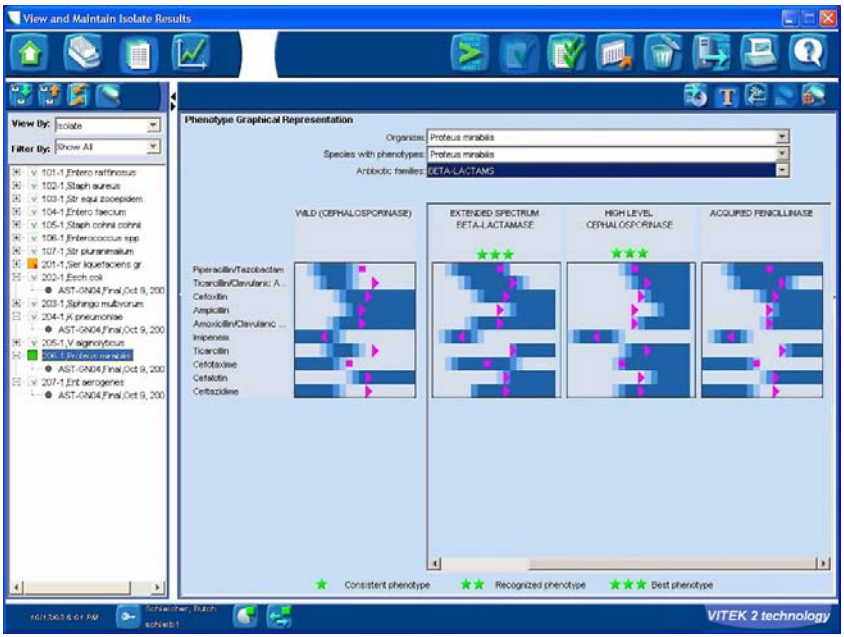

Figure 8-16: AES Graphic

Selecting and Moving a Test

From the View and Maintain Isolate Results view you can navigate among isolate results to view and maintain isolate information and move test cards between isolate groups. By default, the navigation tree is collapsed to the isolate group level and the view is set to **Isolate**. For details, see Expanding and Collapsing the Navigation Tree on page 8-6.

Note: *You can only move test cards between isolate groups that share the same laboratory identification number, isolate number, organism quantity, offline test and results, and bench. The new isolate group must not contain duplicate antibiotics.*

You cannot move a card between isolates if either isolate group has already been reviewed or approved.

1) From the View and Maintain Isolate Results view, expand the isolate group to view the test cards within that isolate group.
2) Select a test card within an isolate group.
3) The test card information appears in the active workspace

4) To move the card to another isolate group, select the card, and drag and drop the card into another isolate group.

Note: *All cards in an isolate group must belong to the same card class. For example, the following are considered invalid: GN and AST-P515 (a gram-negative ID and a gram-positive AST).*

5) After you confirm the move, the system software updates the associated isolate results and the isolate groups.

Note: *If the original isolate group is empty, the system software deletes it.*

6) The workstation reanalyzes the destination isolate group and the original isolate group if necessary.

Viewing Card Details

Depending on which card is selected from within an isolate, you can view the detailed laboratory report information by clicking the **View Card Details** icon.

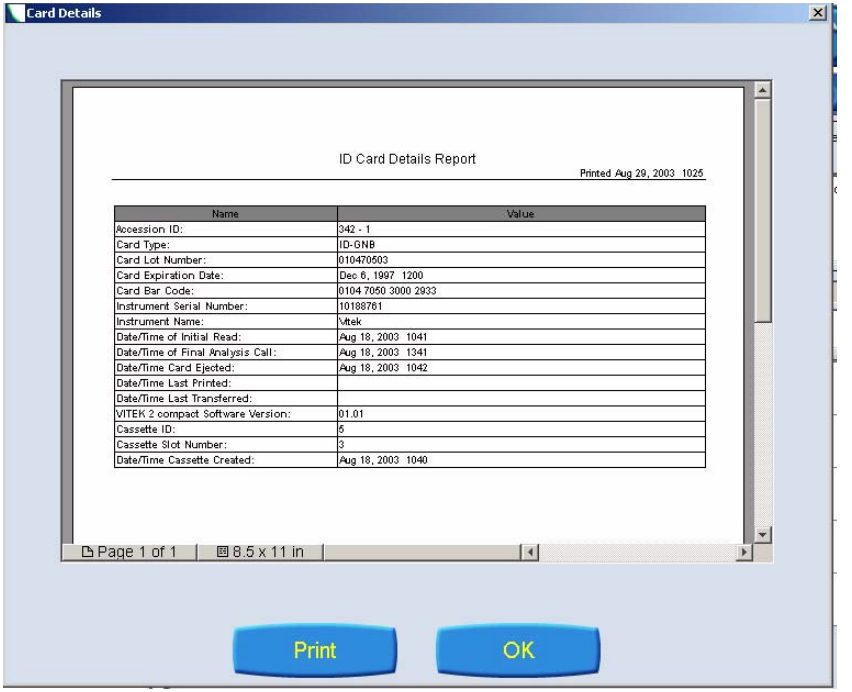

Figure 8-17: View Card Details

Viewing an Isolate Audit Trail

When viewing results, a Supervisor can view the isolate's audit history. The audit history captures the life cycle of an isolate from creation to archive. The audit history also records all user changes.

To view the audit history of an isolate:

1) From the View and Maintain Isolate Results view, select an isolate to view the audit trail.

2) Click the **View Audit History** icon.

Figure 8-18: View Audit History Icon

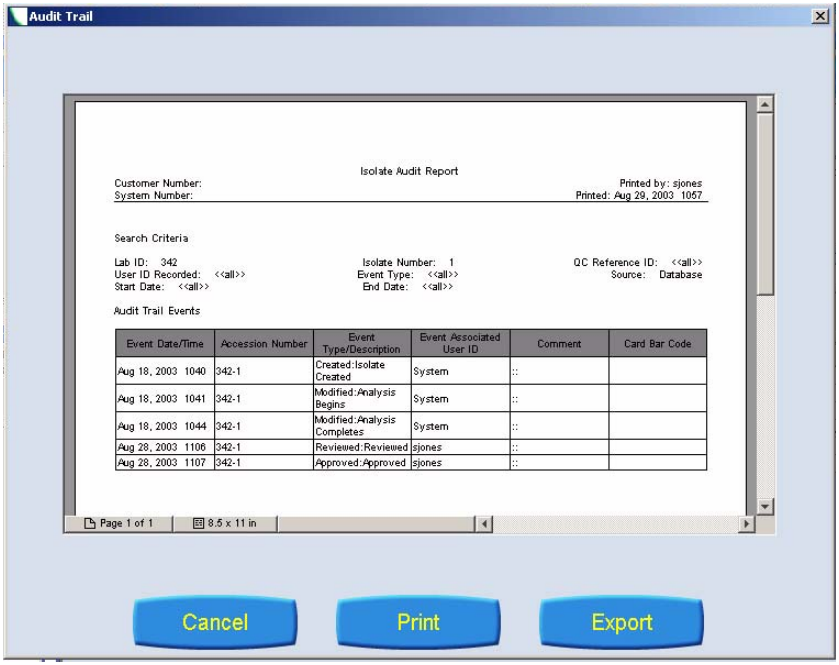

Figure 8-19: View Isolate Audit

3) The isolate audit history displayed in the window is read-only and appears as the information is displayed on the printed report.

4) To print the report click **Print**.

5) To export the report, click **Export** from the window to export the audit trail information to a CD. Make sure a blank CD has been inserted. For details on exporting data, see Chapter 13 Saving Audit Trail to a CD.

Exporting Results and Raw Data to Electronic Media

For support and troubleshooting ID and AST analysis, you can export raw data to a removable media.

To export Isolate and Raw Instrument Data in the form of a report to electronic media:

1) From within the View and Maintain Results view, select the isolate(s) that you want to export.

2) Click **Export Isolate and Raw Instrument Data**.

Figure 8-20: Export Isolate and Raw Instrument Data Icon

3) Insert a blank CD.

Note: *If a CD is not already inserted, a message appears asking you to insert a blank CD.*

4) After you insert the CD, the system software validates the CD and copies the raw instrument data and associated isolate information to the CD.

Sending Biopatterns to SRF (Industrial Use)

Note: *Any lab tech or supervisor can copy biopatterns to the SRF database; however, only a supervisor can view and maintain the SRF database information.*

When you review organism identification results, and the organism results meet the criteria for SRF, you can copy the biopattern to a local database known as the SRF Database. The criteria for copying biopatterns to the database depend on the needs of your individual laboratory.

Note: *If the identification card selected to copy to SRF is part of an isolate group, the isolate group results status must be* **Final***.*

To copy the biopattern to the SRF database:

1) From the View and Maintain Isolate Results view, select the ID results that you want to copy to SRF and click the **Send to SRF** icon.

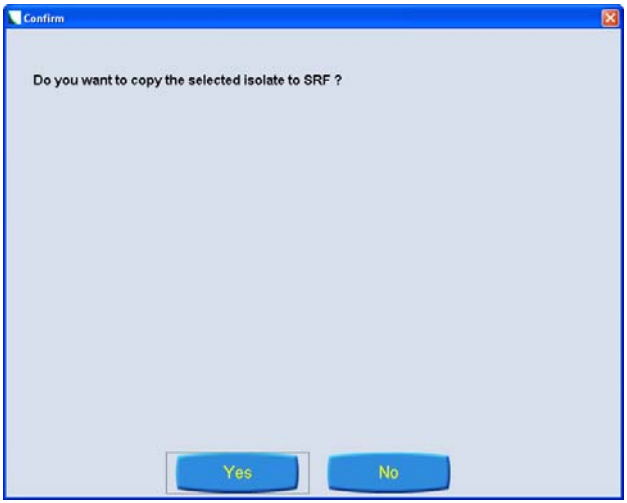

Figure 8-21: Send to SRF

2) A confirmation window appears asking you to confirm copying this biopattern to SRF. Click **Yes** to copy the biopattern.

3) The SRF biopattern information for the isolate is recorded in the local SRF database.

Note: *If the card bar code is already entered, an informational message appears and the SRF is not updated.*

4) To view the SRF organism, go to the View and Maintain SRF Data view. For more details, see Chapter 6 Maintain Supplemental React File (Industrial Use).

Printing Result Reports

From within View and Maintain Isolate Results view, you can print isolate result reports. The following reports are available from the Results view:

- Laboratory Report
- Chart Report
- Detailed Card Report
- Detailed AES Report

Lab Report and Chart Report

A Lab Report and a Chart Report contain report results of ID and AST tests for an isolate group. These reports also contain validation information if AES is enabled. The following table shows the report variations.

Table 8-8: Report Contents

Isolate	Report Sections
ID and AST	ID Summary and AST Details, includes AES if enabled
Only ID test	ID Details
Only AST test	ID Summary, AST Details, includes AES if enabled

The following information is repeated on each page:

- Laboratory Information Number and Isolate number or Accession ID (Chart Report)
- Patient Name (if enabled)
- Patient Identification number (if enabled)
- Patient location (Chart Report Only)
- Name of physician (Chart Report Only)
- Version number, if 21 CFR 11 is enabled
- Isolate Bench (Lab Report Only, if enabled)
- Date/time last modified if 21 CFR 11 is enabled

Note: *If AES is enabled, AES changes and user changes are visually flagged, and antibiotics that were deduced will have a + sign in front of them.*

Note: *Suppressed antibiotics from within results management or user configuration are not printed on the Chart Report.*

On a Lab Report if electronic signature is enabled, the last section of the report contains the following information:

- User ID

- User Name
- Action (reviewed or approved)
- Date/time completed
- Change comment

On a Lab Report, if AES is enabled, the bottom of each page of the Lab Report contains the following:

- MIC Interpretation Guideline
- Therapeutic Interpretation Guideline
- AES Parameter Set Name
- Date and Time AES Parameter Last Modified

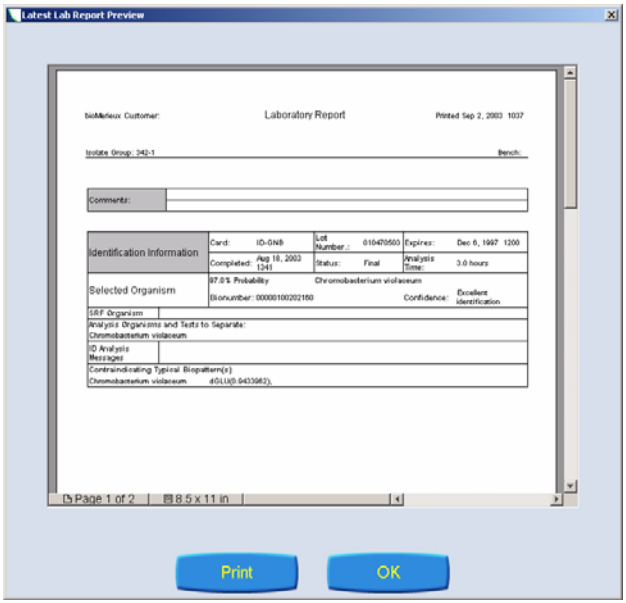

Figure 8-22: Laboratory Report (First Page of ID Summary)

On a Lab Report for each Review and/or Approve if electronic signature is disabled, the last section of the report contains the following information:

- User ID
- Action (reviewed or approved)
- Date/time completed
- Comment

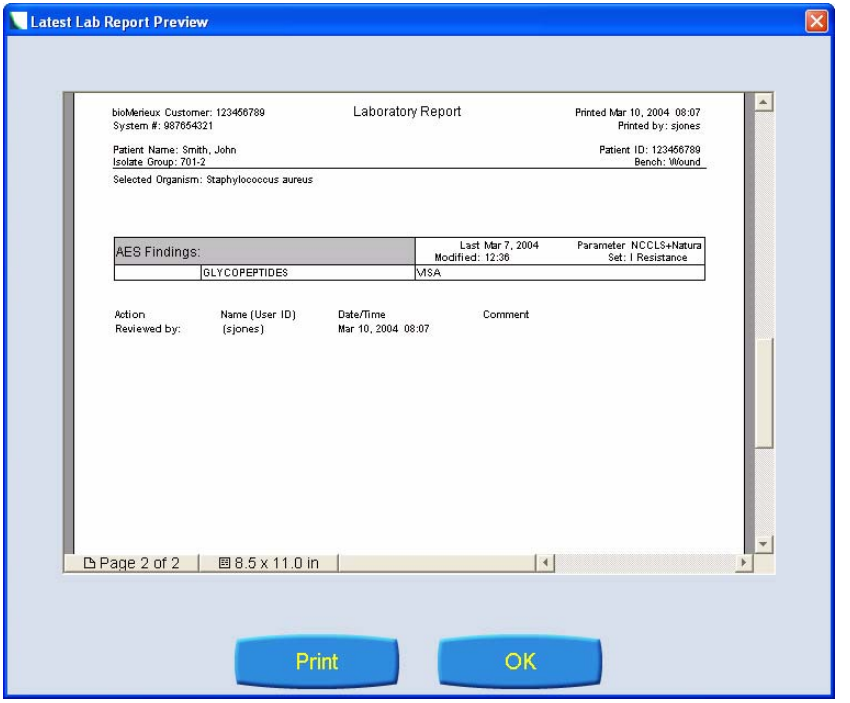

Figure 8-23: Lab Report (Page 2)

Accessing and Printing a Detailed Card Report

To access a detailed card report:

1) From the View and Maintain Isolate Results view, select the card level results that you want to view.
2) Click on the **View Card Details** icon.
3) The Detailed Card Report appears for the card that you selected.
4) Click **Print** to print the report, or click **OK** to return to the Results view.

Note: *When a card under an isolate is printed, the Audit Trail report and the Card Detail report are not updated to show this action.*

Detailed Card Report (ID and AST Details)

The **AST Card Details** report appears displaying details about the AST card processing.

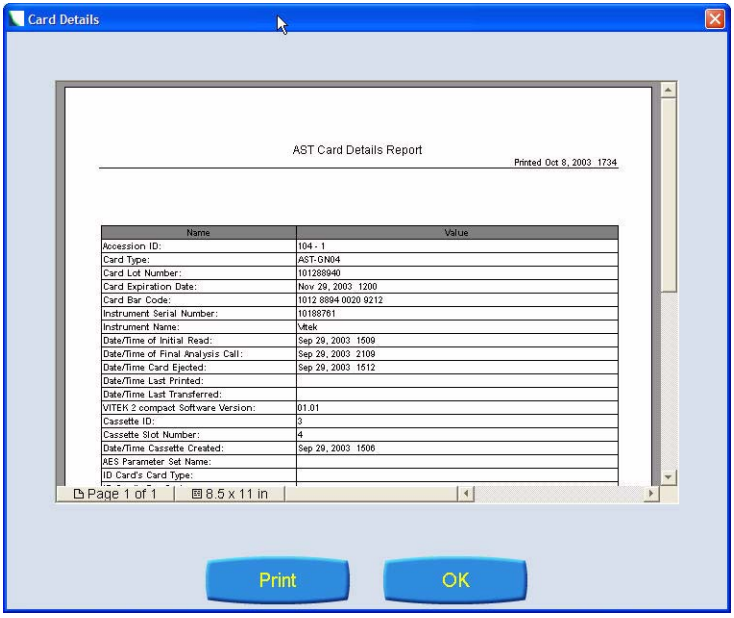

Figure 8-24: AST Card Details Report

The **ID Card Details** report prints details about the ID card processing.

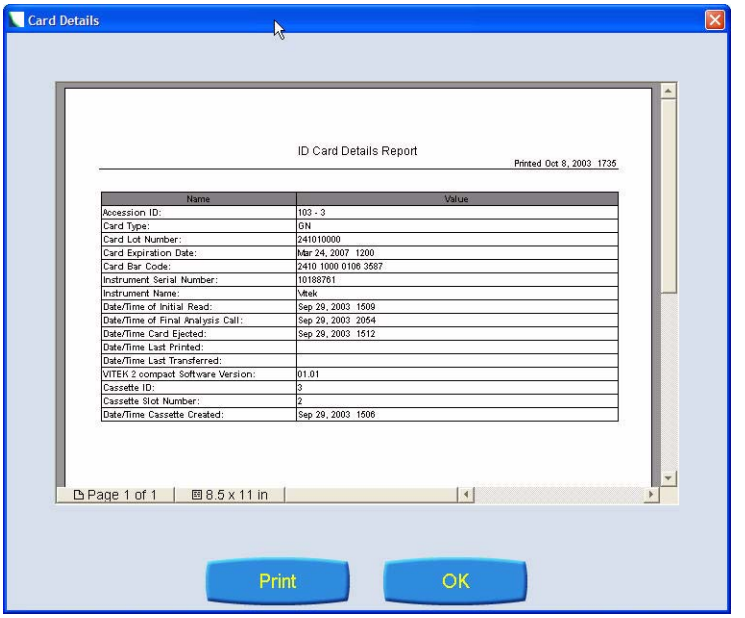

Figure 8-25: ID Card Details Report

Sending Data to LIS

Depending on your BCI configuration settings, the Isolate information is sent to a Laboratory Information System (LIS) either automatically or when a user clicks **Send Data to LIS**.

By default, the isolate information transfers automatically based on your BCI Configuration. For details, see Chapter 12 Configure and Maintain BCI

If Automatic Transfer is disabled, or to send the data upon request:

1) Select the *isolate* group that you want to send to the LIS.

Note: *To send an isolate to an external data management system, the isolate must meet the following criteria:*

- Isolate is not qualified
- Isolate is final
- Isolate does not need to be reviewed

- Isolate does not need to be approved

2) Click the **Send to LIS** icon.

Figure 8-26: Send to LIS Icon

3) The system software creates an upload packet following the configuration parameters. For details see, Chapter 12 Configure and Maintain BCI.

Deleting Cards or Isolate Groups

To delete a card or isolate from the instrument:

1) Select the card or isolate that you want to delete.

2) Click the **Delete** icon.

Figure 8-27: Delete Icon

3) The following message appears.

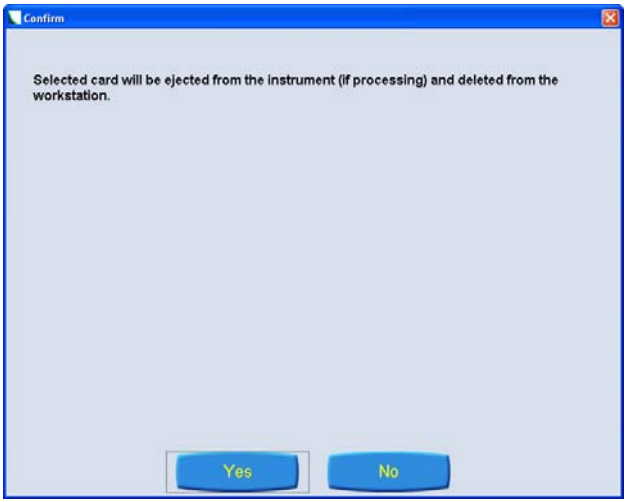

Figure 8-28: Delete Card Message

4) Confirm whether you want to delete the card or isolate group by selecting **Yes** or **No**.

5) If you select **Yes**, the card is deleted from the system software.

Note: *If 21 CFR 11 is enabled, the card is not deleted from the system. The card is flagged.*

Ejecting Cards

To eject a card from the instrument:

1) Select the card that you want to eject.

2) Click **Eject Cards** icon.

Figure 8-29: Eject Card Icon

3) The following message appears.

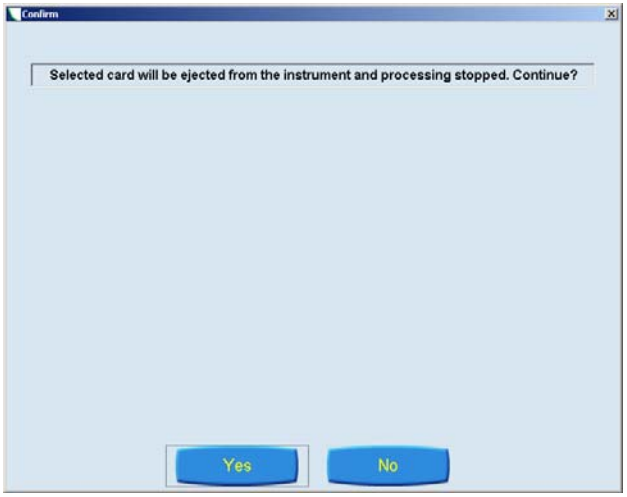

Figure 8-30: Eject Card Message

4) Confirm whether you want to eject the card by selecting **Yes** or **No**.

5) If you select **Yes**, the card is ejected from the instrument.

Reanalyzing Isolate Results

When you make changes to any of the isolate results, you can also reanalyze the results. To do so, click the **Reanalyze** icon.

Note: *You cannot reanalyze an isolate group with only an ID card and SRF disabled.*

Figure 8-31: Reanalyze Results

Review and Approve Results Configuration

When results become final, you may need to review or approve them before the results are sent to the LIS.

Reviewing Results

Results are stopped for review depending on how the results validation is configured for your lab. For Results Validation Configuration details, see Chapter 9 Results Validation Configuration.

To review results:

1) From the View and Maintain Isolate Results view, select an isolate from the navigation tree.

2) If the result status is **To be Reviewed** and you agree with the result, click the **Review** icon.

Note: *If Electronic Signature is enabled, enter your Password to review an isolate.*

Figure 8-32: Review Results

Reviewing Batch Results

To review more than one isolate at a time:

1) From the View and Maintain Isolate Results view, select one or more isolates.

2) To select and review more than one isolate, hold down the **Shift** key and select the consecutive isolates you want to review, or hold down the **Ctrl** key and select the nonconsecutive isolates that you want to review.

3) The selected isolates appear in a list in the active workspace.

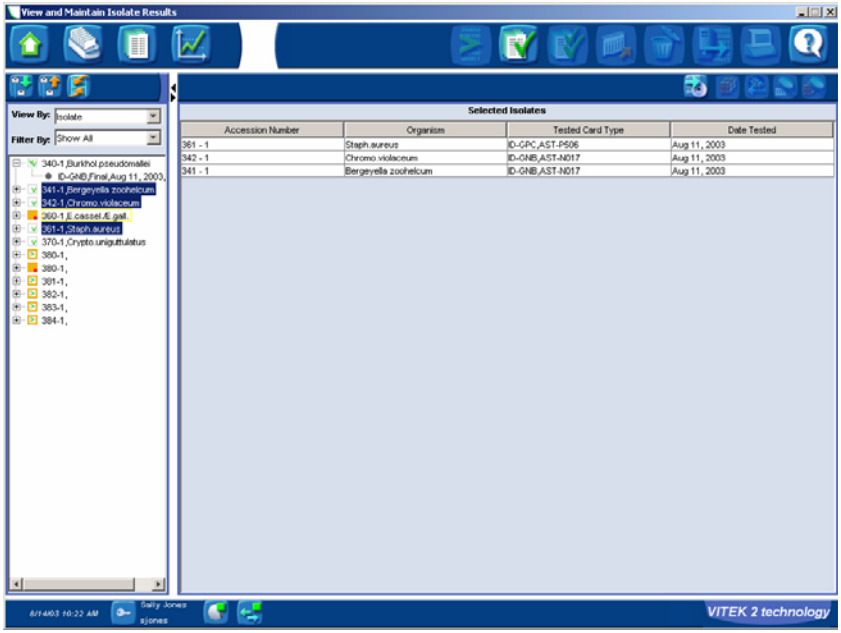

Figure 8-33: Batch Review

4) To review these isolates, click the **Review** icon.

Note: *If Electronic Signature is enabled, enter your Password to batch review these isolates.*

Approving Results

Note: *Only members of the Supervisor group can approve isolates.*

Results will need to be approved depending on how the result validation is configured for your lab. For Result Validation Configuration details, see Chapter 9 Results Validation Configuration.

To approve results:

1) From the View and Maintain Isolate Results view, select an isolate from the navigation tree, and click the **Approve** icon.

Note: *If Electronic Signature is enabled, enter your Password to approve an isolate.*

Figure 8-34: Approve Results

Approving Batch Results

To approve more than one isolate at a time:

1) From the View and Maintain Isolate Results view, select one or more isolates.

2) To select and approve more than one isolate, hold down the **Shift** key and select the consecutive isolates you want to approve, or hold down the **Ctrl** key and select the nonconsecutive isolates that you want to approve.

3) The selected isolates appear in a list in the active workspace.

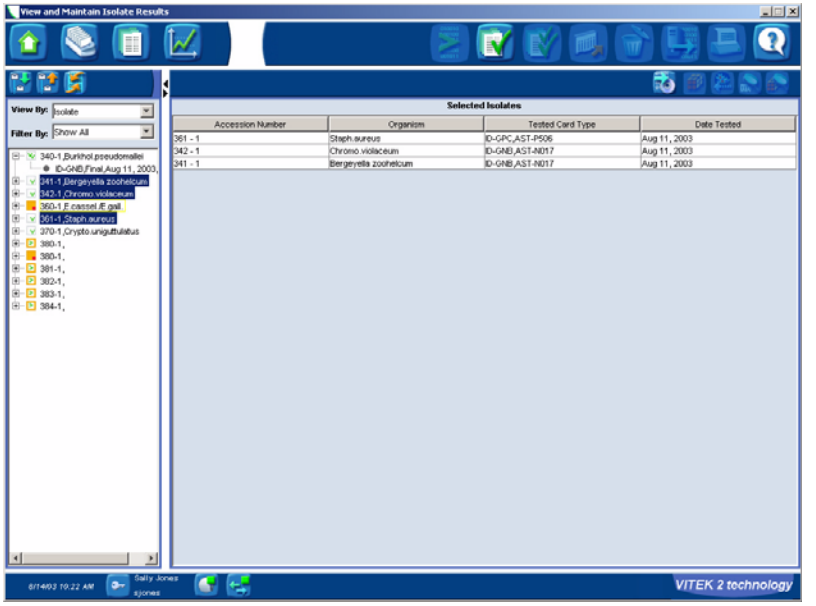

Figure 8-35: Batch Approve

4) To approve these isolates, click the **Approve** icon.

Note: *If Electronic Signature is enabled, enter your password to batch approve these isolates.*

CONFIGURE RESULTS ANALYSIS AND REVIEW 9

About This Chapter

This chapter describes configuring ID and AST analysis. This chapter also covers Results Validation Configuration settings.

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Configuring Result Validation • 9-7

Configuring ID Analysis

Configuring Identification (ID) analysis consists of the following tasks:

- Enable SRF Analysis (Industrial Use)
- Select Organisms for Automatic Slashline Resolution
- Set Time to Eject Analyzed Cards

Note: *To enable SRF, you must select Industry mode from the General Configuration view and select the Enable SRF check box from ID Configuration.*

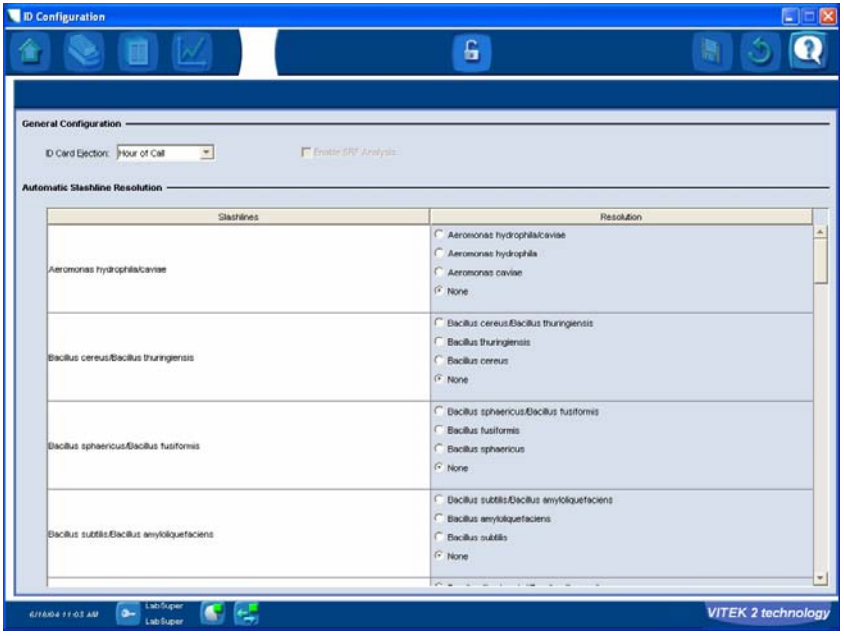

Figure 9-1: Configure ID Analysis

View and Maintain ID Analysis

When you select ID Configuration view, you can view and modify the Identification settings.

Selecting Organisms for Automatic Slashline

When you configure the identification analysis parameters, you have the option to change the automatic slashline resolution for one or more slashline organism groups:

1) From within ID Configuration view, unlock the view to make changes.

2) Use the list and scroll to navigate to the slashline organism group that you would like to change.

3) Make any necessary changes.

4) Be sure to save and lock your changes before moving on to another view.

Enabling SRF Analysis (Industry Use)

SRF Analysis is used in Industry Mode only.

Note: *To enable SRF analysis, the system must be set to **Industry mode** and you will need to select the check box beside **Enable SRF Analysis** in ID Configuration view.*

Setting the Time to Eject Analyzed Cards

When you change the time to eject completed and analyzed cards, you can select the following options from the drop-down list:

- Hour of Call (default) – The hour a card's results become final.
- Max Card Incubation – The maximum incubation time for a particular card.

Configuring AST Analysis

AST analysis determines MIC values from instrument raw data collected from a susceptibility card. You can configure AST Analysis.

Susceptibility configuration consists of the following tasks:

- Select antibiotics to deduce
- Select organism-antibiotic combinations to suppress
- Define the time for card ejection (max incubation / hour of call).

Accessing AST Analysis Configuration

To access AST Analysis Configuration:

1) From the Main view, select **AST Configuration** from the **Configuration** drop-down menu.

2) The AST Configuration view appears.

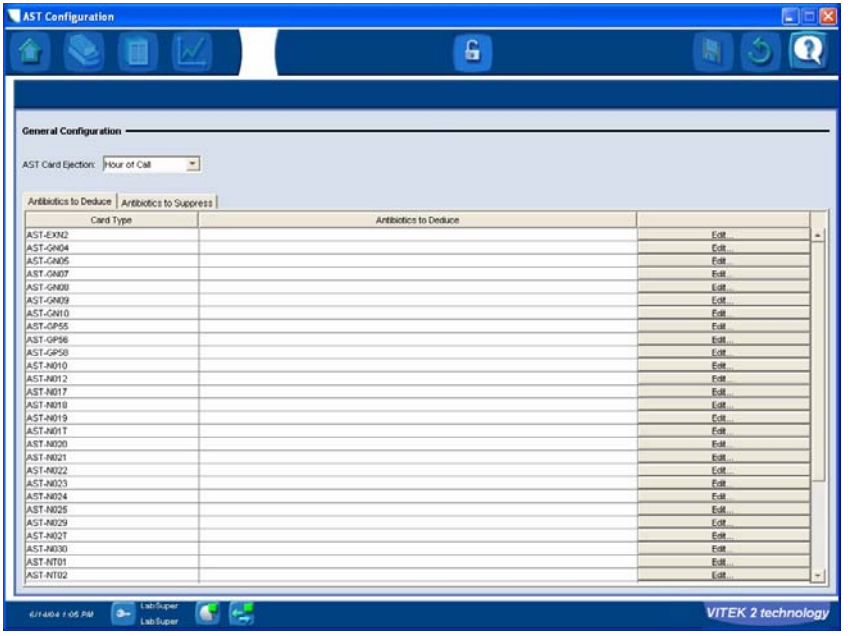

Figure 9-2: AST Configuration View

Card Ejection

When configuring AST analysis, you can set the AST card ejection time. There are two options:

- Maximum Card Incubation (Default)
- Hour of Call

Deducing Antibiotics

When configuring AST card analysis, you can select drugs to deduce based on AST cards. To do so, follow these steps:

1) From within the AST Configuration view, unlock the view to make changes.

2) Scroll to the AST card that you would like to modify.

3) Select **Edit**.

4) A window appears displaying antibiotics to deduce.

5) Select the antibiotics to deduce and click **OK**.

6) Be sure to save and lock your changes before moving on to the next view.

Suppressing Antibiotics

When configuring AST card analysis, you can select antibiotics to suppress based on AST cards.

Note: *If an organism-antibiotic combination is suppressed when AST analysis is complete and AES is performed, the results appear in the active workspace and on the lab report. However, the results do not appear on the Chart Report, and results are not sent to LIS.*

To suppress antibiotics:

1) From within the AST Configuration view, unlock the view to make changes.

2) Select the Antibiotics to Suppress tab.

3) Select the **Add an Organism** icon.

4) A window appears displaying an organism list.

5) Select an organism and click **OK**.

6) Click **Edit**.

7) A window appears displaying antibiotics to suppress.

8) Select the antibiotics to suppress and click **OK**.

Note: *Be sure to save and lock your changes before moving on to the next view.*

Results Validation Configuration

Result Validation Configuration involves configuring results for review or approval, allowing for batch review and approval, and/or enabling electronic signature. If AES is enabled, result validation configuration also includes selecting organism-phenotype combinations to stop for review, enabling review of MIC Corrections, and review of Therapeutic Interpretations.

Critical Isolates

After the workstation software has analyzed the test card readings, isolates with the characteristics noted in the following table will be categorized as **Critical**.

Note: *Critical Isolates must be complete, and must have no other qualifying results.*

Isolates with one or more of the following characteristics are considered **Critical Isolates** and are flagged for review.

Table 9-1: Critical Isolates

Analysis Problem	Description
ID Card Analysis Problems	• Organism result is Unidentified • Analysis indicates an unfilled ID card • ID card status is **Terminated** • Unusual or highly pathogenic organism identifications
AST Card Analysis Problems	• One or more terminated drugs and the card status are not terminated • Insufficient growth in the wells • Card status is **Terminated**

Table 9-1: Critical Isolates

Analysis Problem	Description
AES Analysis Problems	• AES confidence of Inconsistent (the number of MIC corrections allowed has been exceeded) • Isolate with certain phenotypes, therapeutic interpretation changes, and/or MIC corrections (if these are enabled in configuration) • Isolate with an unusual MIC result for one or more antibiotics • Isolate results in an AES confidence of Expert Analysis Not Performed when biologic validation is enabled. • AES proposes a change to the offline test on an isolate. • AES proposes a change to the test performed on an AST card.

Configuring Result Validation

When results are qualified or stopped for any reason depending on how validation is configured, they may need to be reviewed or approved by a Laboratory Technologist or a Supervisor.

1) From within the Result Validation Configuration view, you can configure isolates to stop for review based on your lab's needs.

2) To make changes to the Result Validation settings, click **Unlock**.

3) Make the appropriate selections and changes to customize the isolate results review and approval process.

Note: *By default,* ***Review Critical Isolates*** *is selected.*

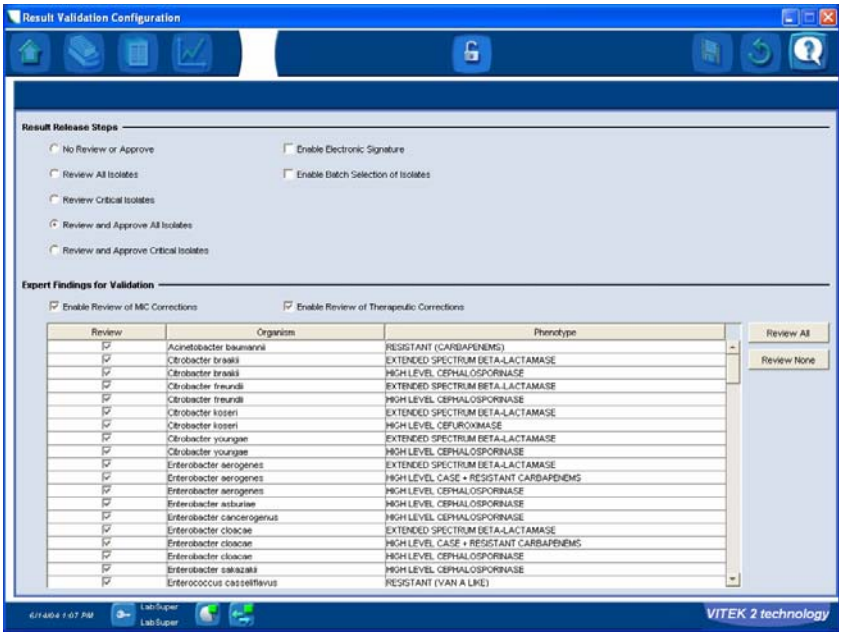

Figure 9-3: Result Validation Configuration

4) Select from the following review options:

Table 9-2: Result Validation Selections

Options	Description	Default Settings
No Review or Approve	Isolates are not stopped for review and are typically sent directly to the data management system.	Disabled
Review All Isolates	All isolates are stopped for review.	Disabled
Review Critical Isolates	Only isolates with unusual findings are stopped for review. For example, an isolate with an organism identification of *Shigella* would be stopped for review.	Enabled
Review and Approve All Isolates	All isolates must be reviewed and approved.	Disabled

Table 9-2: Result Validation Selections

Options	Description	Default Settings
Review and Approve Critical Isolates	Only isolates with unusual findings are stopped for review. For example, an isolate with an organism identification of *Shigella* would be stopped for review.	Disabled

5) The additional result validation settings include the items listed in the following table.

Table 9-3: Result Validations Settings

Options	Description	Default Settings
Electronic Signature	If enabled, requires that a user enter the *User ID* and *Password* to review or approve an isolate.	Disabled
Batch Selection of Isolates	Enable this to allow selection of multiple isolate results for review or approval.	Disabled
Expert Findings/Phenotype Selected for Validation	Select organism-phenotype combinations to stop for review or approval, click **Review ALL** to quickly select all for review. Click **Review None** to deselect all combinations.	None Selected
MIC Corrections	Enable review of MIC corrections.	Enabled
Therapeutic Corrections	Enable the review of Therapeutic Interpretation Corrections.	Enabled

6) Click **Save** when you have made the necessary changes.

7) Click **Lock** to lock the view and then you can move on to another view.

PART IV: CONFIGURE THE WORKSTATION AND MAINTAIN SYSTEM UTILITIES

CONFIGURE AND MAINTAIN WORKSTATION 10

About This Chapter

This chapter covers customizing General Configuration, viewing Versions of Installed Components, and maintaining System and Instrument Status and Alarms.

Note: *Both a Laboratory Technologist and a Supervisor can view configuration settings; however, only a supervisor can modify the configuration parameters.*

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Accessing Configuration Views

The following components are available for configuration:

- View Versions of Installed Components
- General Configuration
- Results Validation (See Results Validation Configuration on page 9-6)
- BCI Configuration (See BCI Configuration Settings on page 12-25)
- AES Configuration (See View and Configure AES on page 11-1)
- AST Configuration (See Configuring AST Analysis on page 9-3)
- ID Configuration (See Configuring ID Analysis on page 9-2)

To access configuration views, follow these steps:

1) From the Main view, click the **Configuration** icon.

Figure 10-1: Configuration Icon

2) Select an option from the **Configuration Option** drop-down menu.

Figure 10-2: ConfiguratIon Drop-Down Menu

3) The Configuration view that you select displays.

Unlock/Lock Configuration View for Changes

Note: *You must be a supervisor to modify configuration settings.*

To make changes to the configuration parameters from within any of the configuration views, you will need to do the following steps:

1) Unlock the view by clicking on the **Unlock/Lock** icon.

Figure 10-3: Unlock Configuration view

2) Make the necessary changes to the configuration settings.

3) Save the changes by clicking **Save**.

Note: *Be sure to save your changes. Changes must be saved to lock the view and move on to the next view.*

4) Lock the view and move on to the next view.

Save or Cancel Configuration Changes

After applying all of the necessary changes to the configuration settings, you need to save and lock the custom changes.

1) From the Configuration views, click **Save** to apply your changes to the configuration settings.

Figure 10-4: Save Icon

2) If you decide to cancel the changes, click **Cancel Changes**. This reverts to the configuration settings applied the last time they were saved.

Figure 10-5: Cancel Changes Icon

3) To apply your changes and move to another view, lock the Configuration view. For details on locking the view, see Unlock/Lock Configuration View for Changes on page 10-3.

General Configuration

As a Laboratory Technologist, you can only view the configuration settings. As a Supervisor you have the option to view and customize the configuration settings. General Configuration settings include the following sections:

- System Information
- System Mode
- Print
- Miscellaneous

To access the General Configuration view follow these steps:

1) From the Main view, select **General Configuration** from the **Configuration** drop-down list.

2) The General Configuration view appears.

Note: *Only a Supervisor can unlock this view to make changes and customize the general features. For a Laboratory Technologist, this view is Read-only.*

Customizing General Configuration (Supervisor Only)

From the General Configuration view you can view and maintain the general settings. To customize the general settings, you need to unlock this screen for changes. For details see Unlock/Lock Configuration View for Changes on page 10-3.

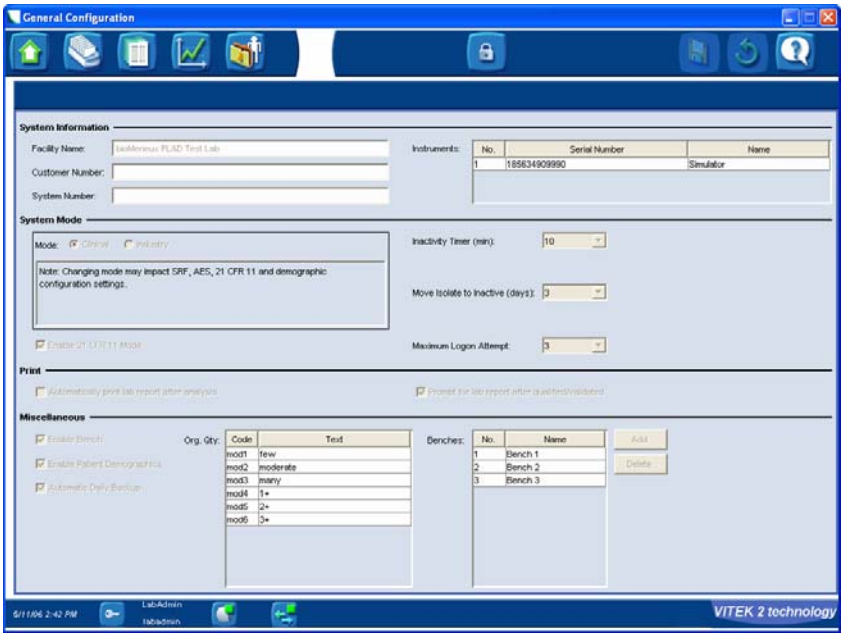


Figure 10-6: General Configuration View

System Information

The system information pertains to the user/customer laboratory specific information and information about the instrument(s) connected to the system software.

The system information includes:

- Facility Name
- Customer Number
- System Number
- Instruments (This includes the Instrument Serial Number and Instrument Name entered at the Instrument. These fields are not editable from the system software)

Note: *The facility name entered here appears on all Laboratory Reports.*

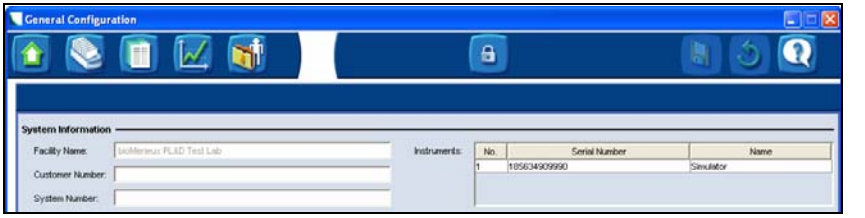


Figure 10-7: System Information

System Mode and Options

The system mode allows you to change the system settings and set system parameters for general features (ex. Maximum Logon Attempts).

Note: *To enable SRF you need to select Industry Mode from the General Configuration view as well as enable SRF from the ID Configuration view.*

The system mode options in this section include the following settings:

- System Mode
- Inactivity Timer
- Move Isolate to Inactive
- Maximum Logon Attempts
- Enable 21 CFR 11 Mode

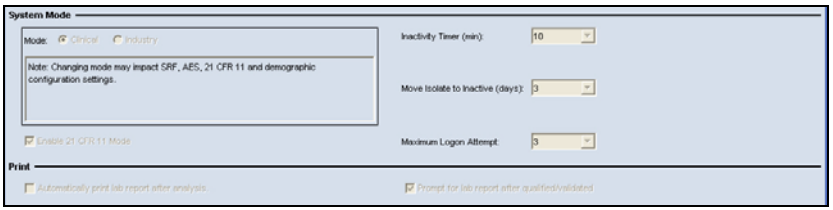


Figure 10-8: System Mode

Setting the System Mode

The system mode can be set to either **Clinical** or **Industry** mode.

Customizing the Inactivity Timer

If the system software remains inactive for a specific period of time, the screen saver appears and the user who was logged into the system software is logged out. If you are a supervisor, you can set the inactivity timer. The default setting is five minutes. The values on the inactivity timer range from one to 60 minutes.

To customize the inactivity timer:

1) From the Main view, select **Configuration View** > **General Configuration.**

2) If you are a Supervisor, you can unlock this view to make changes.

3) To modify the timer, select the time from the **Inactivity Timer (min)** drop-down list.

4) Click **Save** after changes are made to the settings.

5) Click the **Lock** icon to lock this view and move on to other views within the system software.

Moving Isolates to Inactive

This setting allows you to set the number of days an isolate remains available in the active workspace. The default is seven days, and the available range of days to move isolates to the inactive workspace is from three to 30 days.

Note: *Do not reuse Laboratory IDs during the time that the isolates with that Laboratory ID remain in the active workspace.*

Isolates that meet the following criteria will be considered eligible to be moved to the inactive workspace:

- Final Isolates
- Isolates Not Qualified
- Isolates that do not need to be reviewed or approved.

Isolates that cannot be edited are in the inactive workspace. The inactive workspace acts as a repository for laboratory reports and QC laboratory reports. The inactive workspace is maintained by user configuration.

Maximum Logon Attempts

This setting allows you to set the maximum number of logon attempts before a user is locked out of the system. The default is three attempts. The maximum attempts can range from two to eight.

Print Settings

There are two global print settings that you can enable from within the General Configuration view. They include:

- **Automatically print lab report after analysis:** When enabled, a laboratory report automatically prints when the isolate has completed analysis.
- **Prompt for lab report after qualified/validated:** When enabled, the print window appears once an isolate has become final and has already been reviewed or approved based on the configuration.

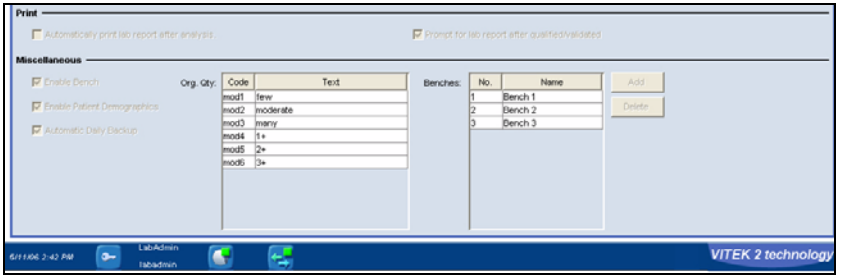


Figure 10-9: Print Settings

Miscellaneous

Setting Up and Creating New Benches (Clinical Use)

The Bench is enabled by default, but you can change this in the General Configuration view. If Bench Area is disabled, it does not appear on laboratory reports or in the general workspace.

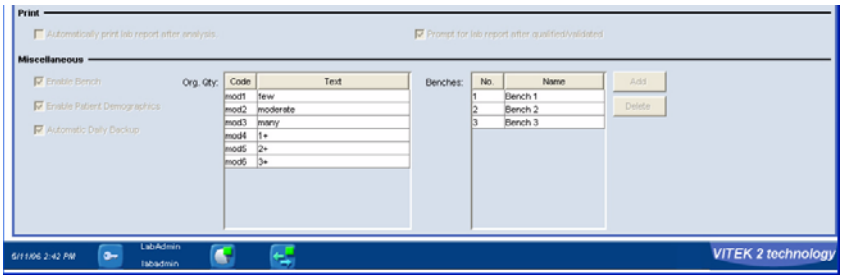


Figure 10-10: Miscellaneous Settings

Add a Bench Name

1) To add a bench name, click **Add**. A new row appears.
2) Place the cursor in the row where you want to add the new bench name.
3) Enter a bench name.

Note: *Press* **Enter** *to create additional bench names before saving the General Configuration.*

4) Click **Save**.

Delete a Bench

1) To delete a bench name select the bench that you want to delete.
2) Click **Delete.**
3) Click **Save**.

Modifying Organism Quantity

In the VITEK® 2 Systems software, the Organism Quantity value is a configurable field attached to an individual cassette.

Modify Organism Quantity Text

1) To modify an Organism Quantity Text field, place the cursor in the row you want to modify.
2) Enter a new alphanumeric value in the Text field row.
3) Press **Enter** to accept the change.

Enabling Patient Demographics (Clinical Use)

Note: *Patient Demographics is disabled by default.*

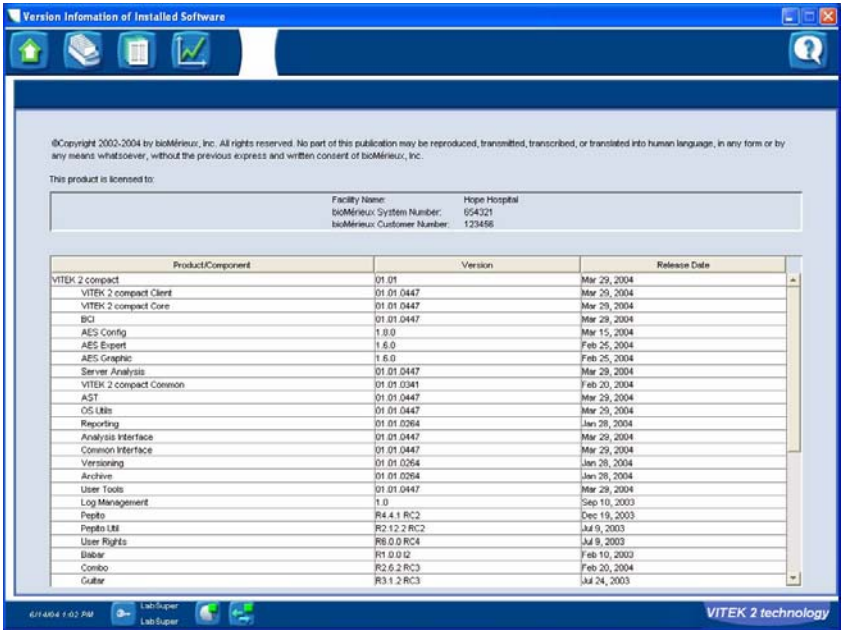
This feature allows you to maintain limited patient demographics through the system software. The patient demographics that appear on the system software include information added from the Manage Patient Information view.

Enabling Automatic Daily Backup

When this feature is enabled, nightly backups of the database can be performed automatically and unattended to a CD. The automatic backup will overwrite any previous data backup on the inserted CD.

Viewing Versions of Installed Components

From the Main view you can select **Version** from the **Configuration** drop-down list to view the currently installed versions of the software components, their version numbers, and release dates.


Version Infomation of Installed Software
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This product is licensed to:
Facility Name: Hope Hospital
bioMérieux System Number: 654321
bioMérieux Customer Number: 123456
Product/Component
Version
Release Date
VITEK 2 compact 01.01 Mar 29, 2004
VITEK 2 compact Client 01.01.0447 Mar 29, 2004
VITEK 2 compact Core 01.01.0447 Mar 29, 2004
BCI 01.01.0447 Mar 29, 2004
AES Config 1.8.0 Mar 15, 2004
AES Expert 1.6.0 Feb 25, 2004
AES Graphic 1.6.0 Feb 25, 2004
Server Analysis 01.01.0447 Mar 29, 2004
VITEK 2 compact Common 01.01.0341 Feb 20, 2004
AST 01.01.0447 Mar 29, 2004
OS Utils 01.01.0447 Mar 29, 2004
Reporting 01.01.0264 Jan 28, 2004
Analysis Interface 01.01.0447 Mar 29, 2004
Common Interface 01.01.0447 Mar 29, 2004
Versioning 01.01.0264 Jan 28, 2004
Archive 01.01.0264 Jan 28, 2004
User Tools 01.01.0447 Mar 29, 2004
Log Management 1.0 Sep 10, 2003
Pepito R4.4.1 RC2 Dec 19, 2003
Pepito Util R2.12.2 RC2 Jul 9, 2003
User Rights R8.0.0 RC4 Jul 9, 2003
Blaster R1.0.012 Feb 10, 2003
Combo R2.6.2 RC3 Feb 20, 2004
Guitar R3.1.2 RC3 Jul 24, 2003
LabSuper
LabSuper
VITEK 2 technology

Figure 10-11: Version View

VIEW AND CONFIGURE AES 11

About This Chapter

This chapter describes viewing and configuring the Advanced Expert System™ (AES).

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Accessing AES Configuration

To access the configuration options for AES:

1) From the Main view, select **Configuration > AES Configuration** from the **Configuration** drop-down menu to view and customize (Supervisor only) the parameter sets.

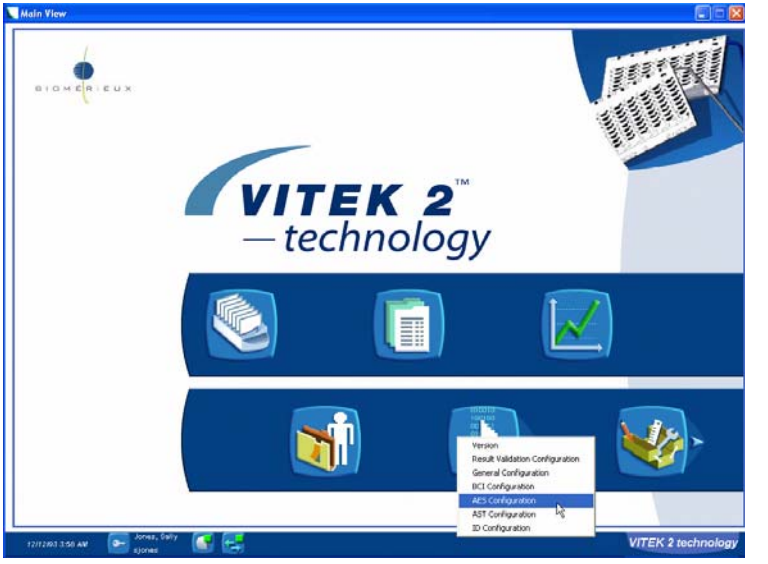

Figure 11-1: Configuration Drop-Down Menu with AES Configuration Selected

2) The AES Configuration view appears.

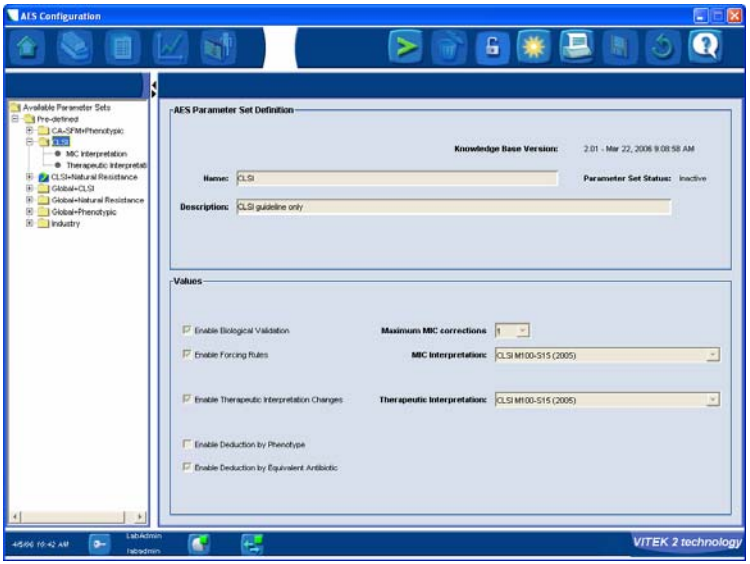

Figure 11-2: AES Configuration View

Note: *Only a Supervisor with privileges to unlock the AES Configuration view can customize AES Configuration.*

3) Click the **Lock/Unlock** icon to unlock this view to make changes.

WARNING

It is recommend that you use the bioMérieux Advanced Expert System™ (AES) as configured by bioMérieux. These settings have been tested to function per the standards organizations and existing data. If you choose to use different criteria, you should follow your institution's internal policies and procedures to verify and validate the adequacy of this criteria. bioMérieux is not responsible for any settings or configuration that differs from the bioMérieux configuration as bioMérieux is not able to ascertain the accuracy of such configurations.

Note: *A warning appears.*

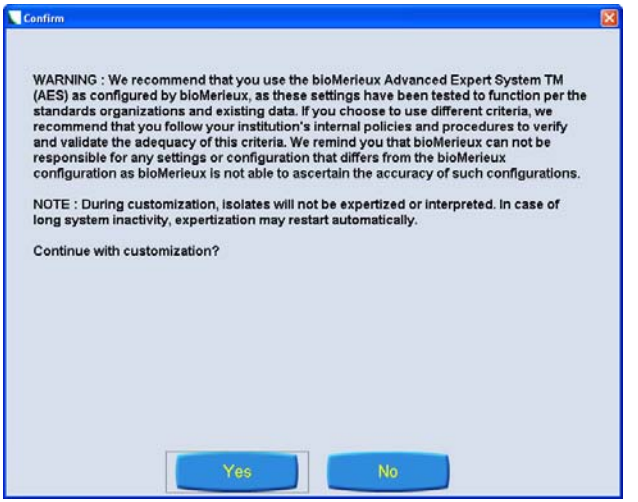
Confirm
WARNING : We recommend that you use the bioMerieux Advanced Expert System TM (AES) as configured by bioMerieux, as these settings have been tested to function per the standards organizations and existing data. If you choose to use different criteria, we recommend that you follow your institution's internal policies and procedures to verify and validate the adequacy of this criteria. We remind you that bioMerieux can not be responsible for any settings or configuration that differs from the bioMerieux configuration as bioMerieux is not able to ascertain the accuracy of such configurations.
NOTE : During customization, isolates will not be expertized or interpreted. In case of long system inactivity, expertization may restart automatically.
Continue with customization?
Yes
No

Figure 11-3: AES Configuration Warning

4) Click **Yes** to acknowledge the warning. This unlocks the AES Configuration view for changes.

Note: *When customizing AES Configuration, validation and interpretation of AST results is suspended until all of your changes are saved or you exit the Customization (unlocked) mode. If the inactivity timer is exceeded, the results restart and are no longer suspended for customization. Any saved changes are applied to the results and any unsaved changes are no longer available.*

Parameter Set Information

The AES Configuration view allows you to view predefined or standard parameter sets. A parameter set is a collection of parameters that you can use to customize the validation and interpretation process within AES. Within this collection there are two very importance parameters.

- **MIC Interpretation guideline —** Defines a set of breakpoints.
- **Therapeutic Interpretation guideline —** Defines the therapeutic interpretations.

The parameter sets appear in the navigation tree in the AES configuration view.

Note: *The default active parameter set is CLSI+Natural Resistance.*

The following predefined or standard parameter sets are available:

- **CA-SFM+Phenotypic —** CA-SFM breakpoints with Phenotypic Therapeutic Interpretations.
- **Global+CLSI —** Consists of Global (CLSI™, CA-SFM, or Manufacturer) breakpoints with CLSI Therapeutic Interpretation Changes.
- **Global+Natural Resistance —** Consists of Global (CLSI, CA-SFM, or Manufacturer) breakpoints with CLSI and Natural Resistance Therapeutic Interpretation Changes.
- **Global+Phenotypic —** Consists of Global (CLSI, CA-SFM, or Manufacturer) breakpoints with Phenotypic Therapeutic Interpretation Changes.
- **Industry —** CLSI breakpoints with CLSI Therapeutic Interpretations with biologic validation disabled.
- **CLSI —** CLSI breakpoints with CLSI Therapeutic Interpretations.
- **CLSI+Natural Resistance —** CLSI breakpoints with CLSI and Natural Resistance Therapeutic Interpretations.

You cannot change the predefined/standard parameter sets, but if you are a Supervisor, you can make a copy of a predefined parameter set to create a new custom parameter set. For details, see Creating a Custom Parameter Set on page 11-10.

AES Configuration View

When you select a parameter set, the following AES Configuration information pertaining to the selected parameter set appears in the workspace.

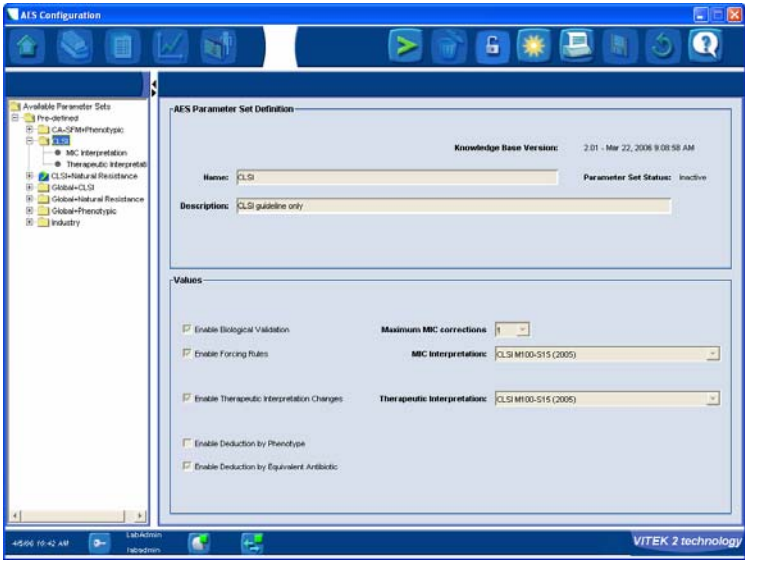

Figure 11-4: AES Configuration View

AES Parameter Set Definition

Name — Name of the standard or custom (must be unique) parameter set.

Description — Information that further describes the parameter set.

Knowledge Base Version — Displays the Knowledge Base version currently defined for analysis.

Parameter Set Status — Displays the status of the selected parameter set. The parameter set may be active or inactive. If active, this parameter set will be used for AES validation and interpretation.

Values

Enable Biologic Validation — If enabled, the process of testing whether observed susceptibility results are consistent with the organism identification

and, if not, proposing the best biological change that makes the susceptibility results consistent with the organism identification.

Enable Forcing Rules — If enabled, the system software applies specific therapeutic changes as defined in the active MIC Guideline. For details, see Appendix B: Forcing Rules**.**

Enable Therapeutic Interpretation Changes — The modification of the interpretation result for an antibiotic, based on proposed phenotypes.

Deductions

AES has the ability to deduce the interpreted result for an antibiotic which has not been tested on a VITEK® 2 instrument but for which the user would like to obtain results. Deduced antibiotics will only report an interpretive category result and will be noted with a +. The user must configure each card type to obtain deduced antibiotic results. For details see Chapter 9 Configure Results Analysis and Review.

Deduction by Phenotype

Enable Deduction by Phenotype — For deduction based on phenotypes, AES uses the MIC distributions and the therapeutic interpretations for the phenotypes recognized.

Phenotype recognition is the second method for antibiotic deduction. For recognized phenotypes during the AES analysis, antibiotics that were not tested and that span only one interpretation category are reported as deduced. If the MIC distribution spans more than one category but a therapeutic change should be performed based on the phenotype, the deduced results are reported. When more than one phenotype is a possibility, the most resistant possibility is reported.

Equivalent Deductions

Enable Deduction by Equivalent Antibiotic — For deduction based on equivalent antibiotics, AES activates the antibiotic deduction rules corresponding to the active interpretation guideline. For details, see Appendix C: AES Antibiotic Deduction Rules by Therapeutic Interpretation Guideline.

For the equivalent deduction method, the observed interpretation of the tested antibiotic is reported as the interpreted result for the requested deduced antibiotic. The rules governing the strict deduction of antibiotics are contained in the interpretation guidelines and are based on national committee recommendations.

Settings

Maximum MIC Corrections — Maximum number of antibiotics and/or tests that can be changed to match a phenotype.

Note: *The maximum number of MIC corrections is an integer from 0 to 2. The maximum number of MIC corrections by default has a value of 1.*

MIC Interpretation — The interpretation guidelines (such as CLSI, CA-SFM, Global) applied to the MIC results.

Therapeutic Interpretation — The therapeutic interpretation guideline applied based on the recognized phenotype(s).

Activating a Parameter Set

The active parameter set appears in the navigation tree and is flagged with the active icon. You can view inactive parameter sets, but a parameter set will not become active until you activate it.

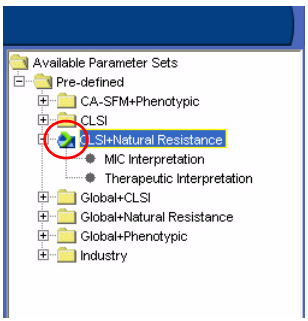

Figure 11-5: AES Active Parameter Set

Only one parameter set is active at a time. The guidelines associated with the active parameter set are considered the active guidelines for system software analysis and interpretation.

The parameter set used for AES can be changed by activating a new parameter set. To do so follow these steps:

Note: *To activate a parameter set you must be at the parameter set level.*

1) Select the parameter set that you would like to activate.

2) Click **Activate Current Parameter Set**.

3) When this occurs, a confirmation message displays.

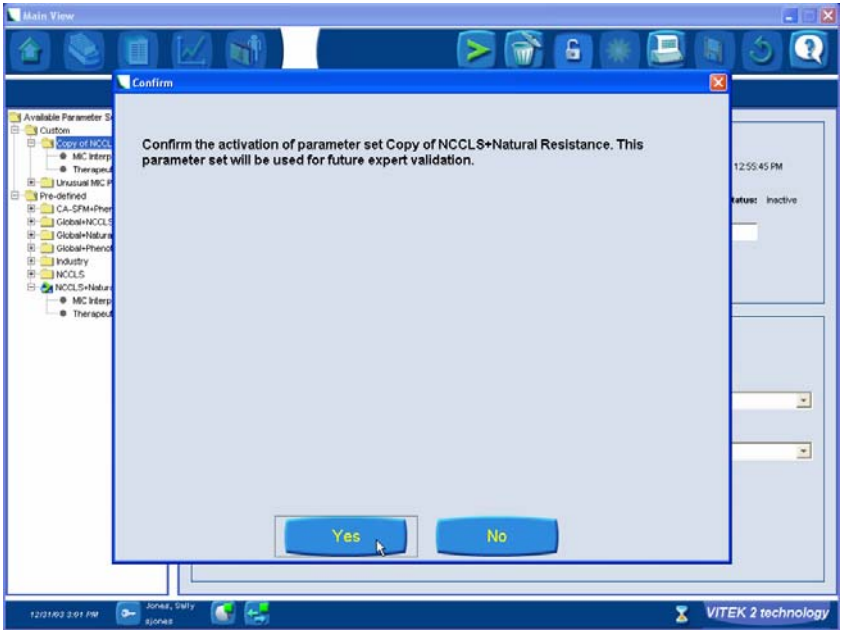
Main View
Confirm
Confirm the activation of parameter set Copy of NCCLS+Natural Resistance. This parameter set will be used for future expert validation.
Yes
No
VITEK 2 technology

Figure 11-6: Activate Parameter Set Confirmation Message

4) Click **Yes** if you want to activate the selected parameter set.

Note: *Activating one parameter set automatically deactivates the previous active parameter set.*

Creating Custom Parameter Sets

AES Configuration allows supervisors to customize the AES Expertise component of the system software. The laboratory technologist can only view the AES configuration settings. The Supervisor can view, create, modify, or delete configurations, but a supervisor cannot alter the pre-defined parameter sets.

Note: *Predefined parameter sets can never be modified or deleted.*

Creating a Custom Parameter Set

To create a new custom parameter set based on a predefined parameter set, follow these steps:

1) Select the base parameter set.

2) Click **Create New Component**.

Figure 11-7: Create New Component Icon

3) Enter a unique *name* and *description* to the new parameter set.

Note: *A parameter set name has to be unique in the knowledge base. A message appears requiring that you enter the correct information if the parameter set name already exists, or if the name is left blank.*

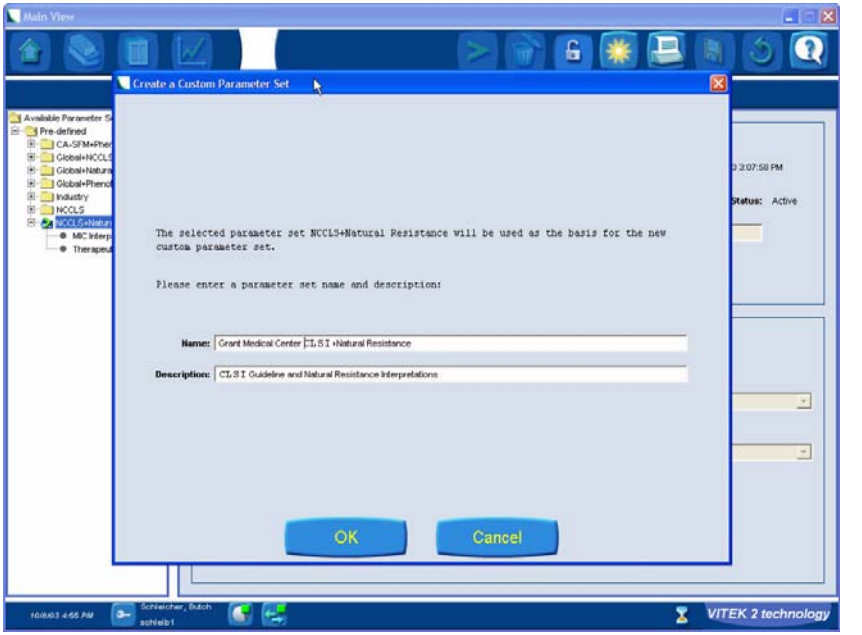
Main View
Create a Custom Parameter Set
The selected parameter set NCCLS+Natural Resistance will be used as the basis for the new custom parameter set.
Please enter a parameter set name and description:
Name:
Description:
OK
Cancel
VITEK 2 technology

Figure 11-8: Create a Custom Parameter Set

4) Click **OK** to create a copy of the predefined parameter set.

5) The custom parameter set appears in the navigation tree.

Note: *Only custom parameter sets can be modified.*

6) The new parameter set is already selected when it is created.

Deleting Custom Parameter Sets

Only custom parameter sets can be deleted. However, a custom parameter set cannot be deleted if it is the active parameter set. Deleting a custom parameter set also deletes the associated custom interpretation guidelines, as long as there are no other parameter sets referenced by the custom interpretation guideline.

To delete a parameter set follow these steps:

1) Select the parameter set you want to delete.

2) Click **Delete**.

3) If this parameter set can be deleted, you will need to confirm deletion of this parameter set and its associated MIC and Therapeutic Interpretation guidelines.

Note: *If you change the MIC or Therapeutic Interpretation Guideline for a custom parameter set, the custom guidelines are deleted if no other parameter set references it.*

Viewing MIC Interpretation Guideline

From within the AES Configuration view, you can select the parameter set in the navigation tree. When the parameter set is fully expanded you can select the MIC Interpretation Guideline to view in the active workspace.

When selecting the MIC guidelines for a particular parameter set, the name, knowledge base version, parameter set status, and breakpoint information is displayed.

CAUTION: When you view an Interpretation Guideline on an inactive parameter set, the status indicates "Inactive" although the guideline displayed may in fact be active, if it is linked to the active parameter set.

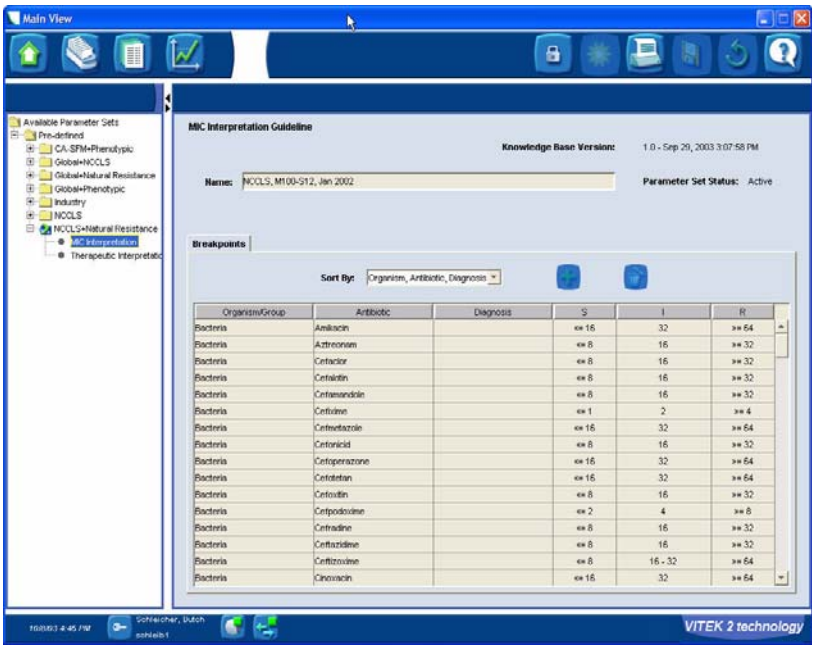

Figure 11-9: MIC Interpretation Guidelines

Customizing MIC Interpretation Guideline

An MIC Interpretation Guideline is part of a parameter set; however, you can only modify the breakpoints of the MIC Interpretation Guideline.

Note: *On a predefined parameter set, all fields are read-only.*

To create a new guideline, follow these steps:

1) From the navigation tree, select the specific guideline under the Parameter Set that you want to modify or use as a basis for a new MIC guideline, and click **Create New Component**.

Figure 11-10: Create New Component Icon

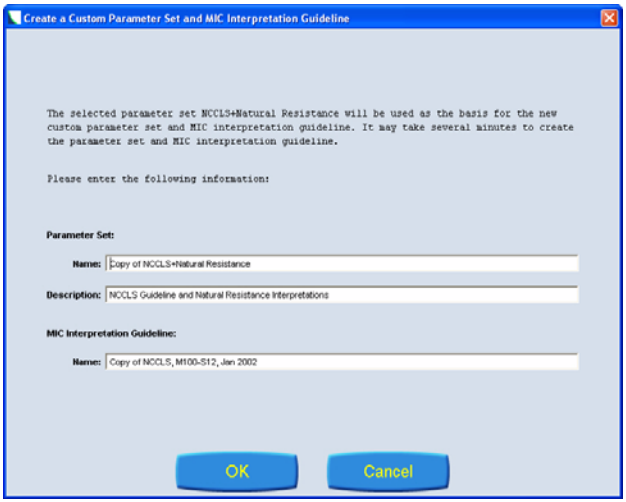
Create a Custom Parameter Set and MIC Interpretation Guideline
The selected parameter set NCCLS+Natural Resistance will be used as the basis for the new custom parameter set and MIC interpretation guideline. It may take several minutes to create the parameter set and MIC interpretation guideline.
Please enter the following information:
Parameter Set:
Name: Copy of NCCLS+Natural Resistance
Description: NCCLS Guideline and Natural Resistance Interpretations
MIC Interpretation Guideline:
Name: Copy of NCCLS, M100-S12, Jan 2002
OK
Cancel

Figure 11-11: Create Custom Parameter Set

2) Enter a unique *Name* for the parameter set and a unique *Name* for the guideline.

Note: *If the current parameter set is predefined, the name and description appear in the navigation zone with the new guideline.*

3) The system software will make a writable copy out of the current predefined guideline.

Note: *The new interpretation guideline name must be unique. If the name entered already exists or if the name is blank, an error message appears with instructions on how to completely customize the guideline.*

Modifying Breakpoints for a Custom Interpretation Guideline

To modify the interpretation guideline name, you must be on a custom parameter set.

You can make the following changes:

- Update a breakpoint value with a new value
- Add a breakpoint value
- Remove a breakpoint value

Updating a Breakpoint

To modify breakpoints:

1) Select an existing breakpoint.

Note: *A blank value means there is no known value for that MIC value.*

2) Make a change to the MIC value of a breakpoint, by selecting from the list of MIC values proposed by the system software.

3) Save the change.

Note: *Customized information appears highlighted.*

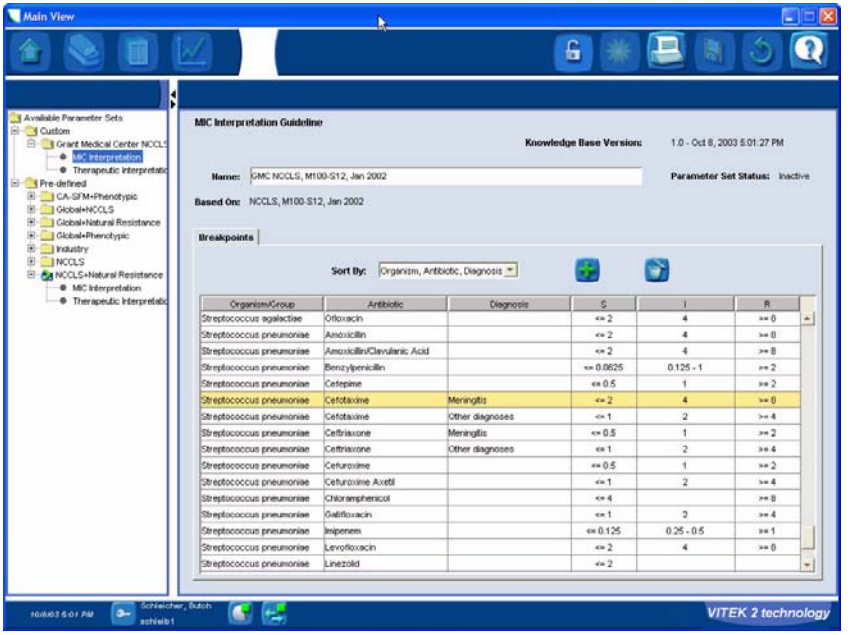

Figure 11-12: Modify Breakpoints

Adding a Breakpoint Set

If you need to update the breakpoints for a custom parameter set, you can add breakpoints:

1) Select the breakpoint.

2) Click the **Add Sign** icon to add a **Breakpoint Set.**

3) The system software displays the following:

- Organism hierarchy

- Antibiotic hierarchy
- Infection Site list

4) Indicate which breakpoint you want to add from the lists of available Organisms, Antibiotics, and Diagnosis.

5) To expand the organism hierarchy, double-click the selection. Only one of each can be set at one time.

6) Click **Next** to go to the next list.

Note: *If you do not want to differentiate breakpoints by diagnosis, select other diagnoses.*

7) The system software makes the updates when you save the changes.

8) Now, you can access the values of the new breakpoint set.

Delete Breakpoint Set

1) Select the breakpoint set that you want to delete and click **Delete**.

2) Confirm the deletion.

Sorting Information

The status of the parameter set appears in the workspace area. You can sort the displayed data by choosing the corresponding value of the **Sort By** drop-down menu.

Note: *You can also choose the order of the columns using drag and drop. Dragging and dropping the columns has no impact on the sorting of the data contained in each column.*

Viewing Therapeutic Interpretation Guideline

To find the Therapeutic Interpretation Guideline for a parameter set:

1) Click on either a predefined or custom parameter set.
2) Select **Therapeutic Interpretation Guideline**.
3) The information appears in the workspace area.

Note: *If the current guideline is a custom guideline, the **Based On** field displays the name of the guideline that the custom guideline is based on.*

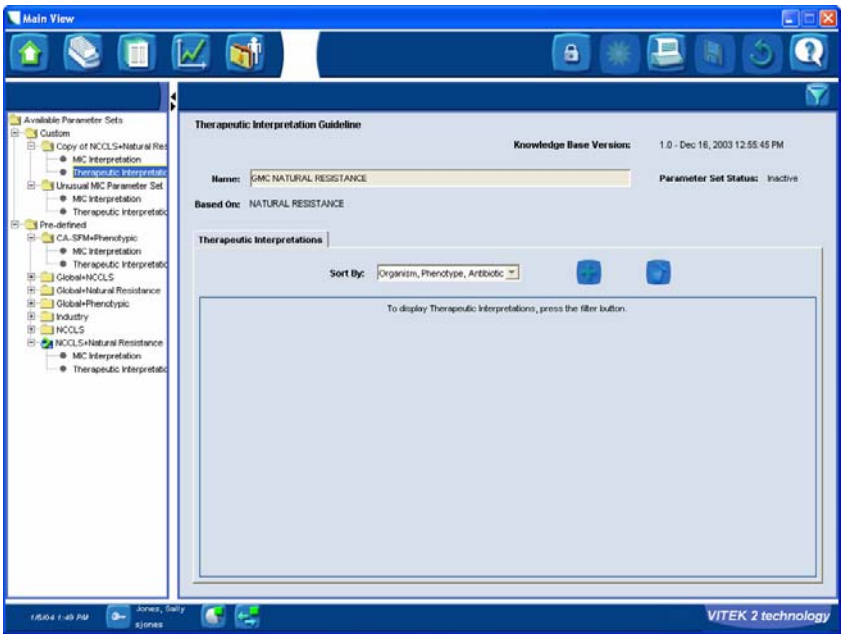

Figure 11-13: View Therapeutic Guideline

To view the specific Therapeutic Interpretation Guideline information used with the current parameter set:

1) Click **Filter**.

Figure 11-14: Filter Icon

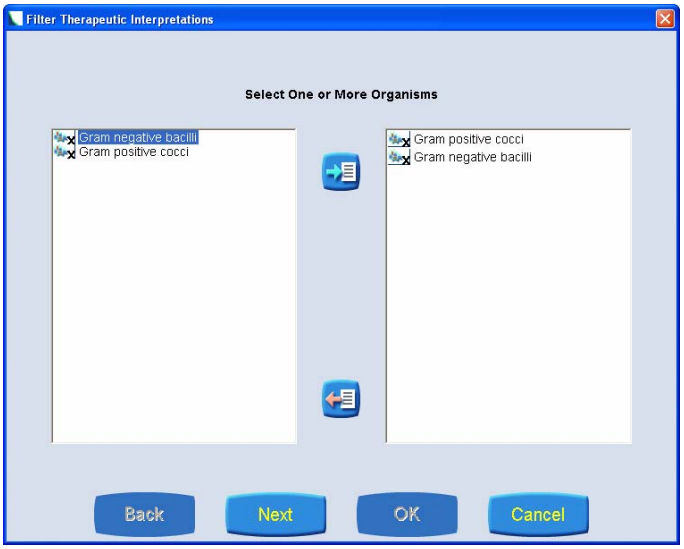

Figure 11-15: Select One or More Organisms

2) To expand the organism hierarchy, double click the selection.

3) Select one or more organisms.

4) Click the **Arrow** icon to include them.

Figure 11-16: Arrow Icon

5) When you have selected the organism, click **Next**.

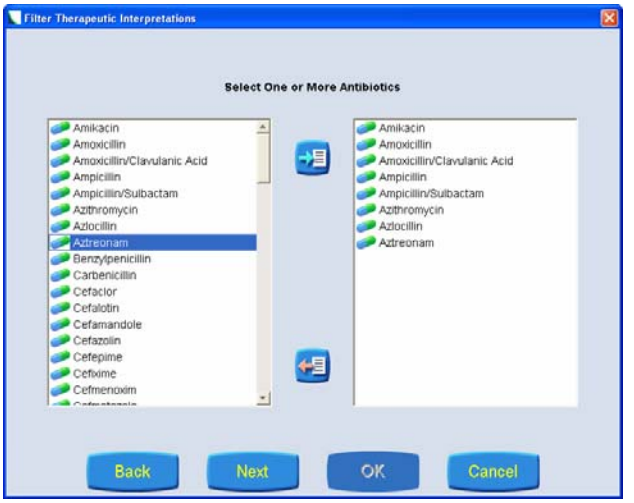

Figure 11-17: Select One or More Antibiotics

6) Select the antibiotics and click the **Arrow** icon to include them. Use **Shift** or **Ctrl** to select multiple antibiotics.

7) Click **Next** when you have made your selections.

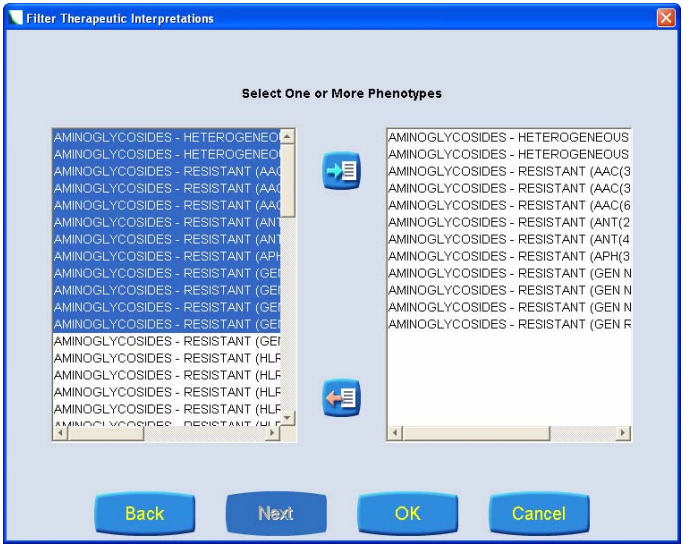

Figure 11-18: Select One or More Phenotypes

8) Select the phenotypes and click the **Arrow** icon to include them.

9) Click **OK** when you have made your selections.

Sorting Information

The status of the parameter set appears in the workspace area. You can sort the displayed data by choosing the corresponding value of the **Sort By** drop-down menu.

Note: *You can also choose the order of the columns using drag and drop. Dragging and dropping the columns has no impact on the sorting of the data contained in each column.*

Creating a Custom Therapeutic Interpretation Guideline

To create a new custom guideline, follow these steps:

Note: *To change the interpretation guideline name, you must be on a custom parameter set.*

1) Select the specific guideline under the parameter set that you want to modify, and click **New Component**.

2) Change the *Name* of the new custom guideline to save it and update the parameter set.

Note: *The new interpretation guideline name must be unique. If the name entered already exists or if the name field is blank an error message appears with instructions on how to completely customize the guideline.*

3) Click **OK**.

4) The system software creates a custom, writable copy of the current, predefined guideline before you can customize it.

Modifying Custom Therapeutic Interpretations

To change the value of a therapeutic interpretation, the user has to pick from a list of values proposed by the system software. To change the Therapeutic Interpretation, follow these steps:

1) Select a custom Therapeutic Interpretation Guideline.

2) Select the organisms, antibiotics, and phenotype to view using the filter.

3) Select one of the Therapeutic Interpretations.

4) Make a change to the custom, interpretation column.

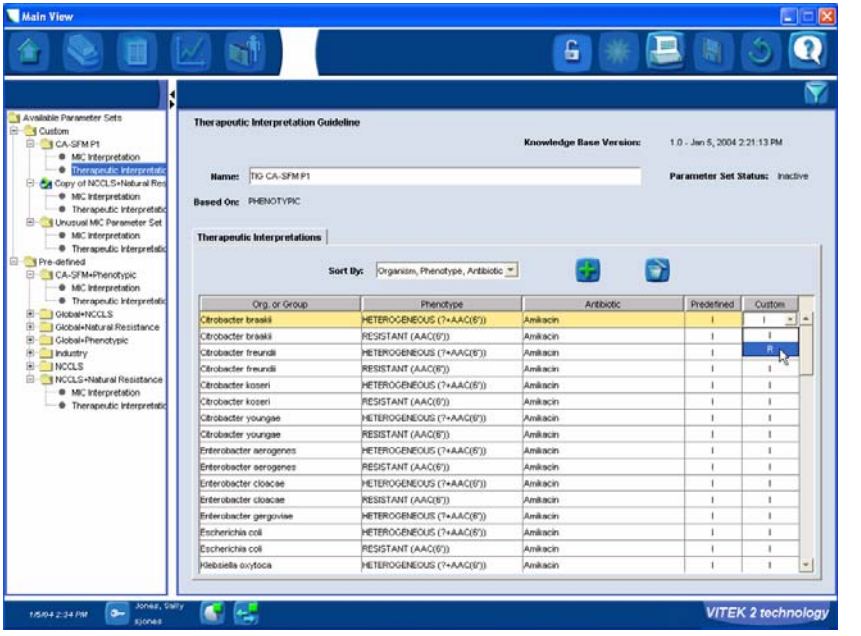

Figure 11-19: Modify Custom Column

5) The therapeutic interpretations are updated based on the changes.

Note: *The custom information appears highlighted.*

Add Therapeutic Interpretation

To add a Therapeutic Interpretation to a custom therapeutic interpretation guideline:

1) From a Custom Therapeutic Interpretation Guideline, click the **Add Sign** icon**.**

Figure 11-20: Add a New Therapeutic Interpretation

2) Filter to select the Organism, Antibiotic, and Phenotype combination to add a new therapeutic interpretation guideline.

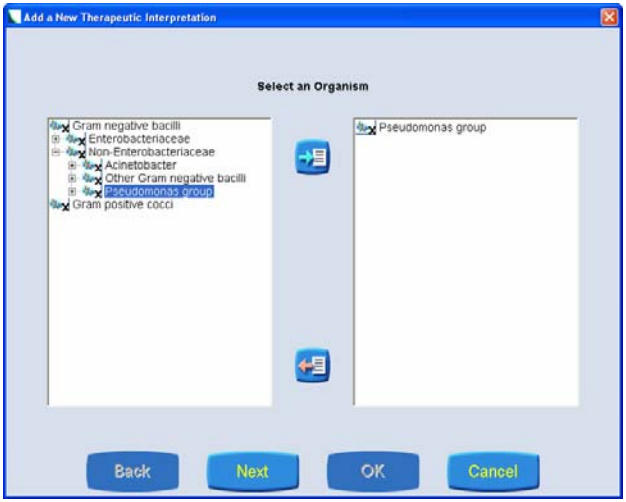

Figure 11-21: Select One or More Organism

3) Select one or more organisms and click the **Arrow** icon to include it. When you have finished making the organism selection, click **Next**.

4) Double click to expand organism choices.

Note: *Only one selection is allowed.*

5) Select the antibiotic and click the **Arrow** icon to include it. Click **Next** when you have made your selections.

6) Select a phenotype and click the **Arrow** icon to include it. Click **OK** when you have made you selection.

7) The new therapeutic interpretation appears in the workspace area.

Delete Therapeutic Interpretations

1) Select the Therapeutic Interpretations that you want to delete.

2) Click **Delete**.

Printing User Change Report

Print the **User Changes Report** to review every variance in all existing custom parameter sets or guidelines. For every change to a predefined parameter set, the custom parameter set value appears in the table on the report.

The user change report:

- Compares the custom parameter set with the predefined parameter set used as a basis.
- Contains all differences between the custom parameter set and the predefined parameter set.

To generate a User Change Report:

1) Click on the **Print User Changes Report** icon.

2) The report corresponding to the current workspace appears in a Print Preview view.

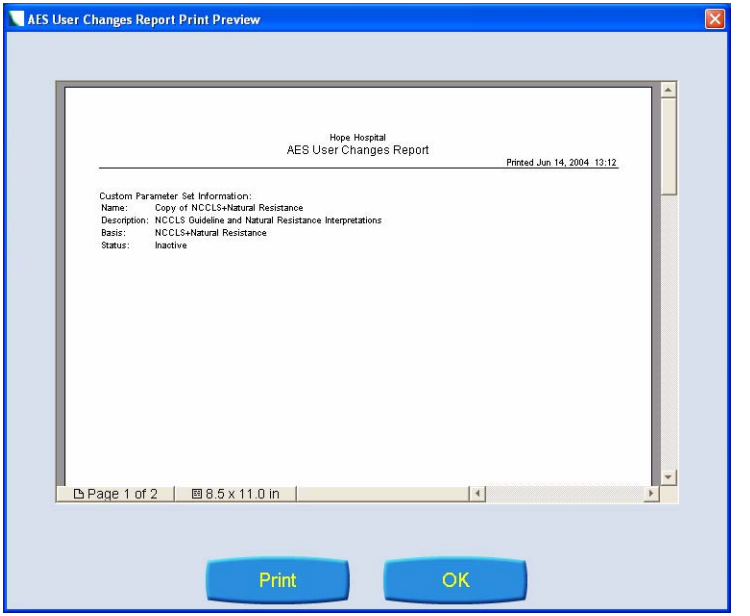

Figure 11-22: User Changes Report

CONFIGURE AND MAINTAIN BCI 12

About This Chapter

This chapter describes viewing and maintaining the Bidirectional Computer Interface (BCI). BCI manages system software interface connections with internal or external data management systems such as Laboratory Information Systems (LIS).

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Introduction

The Bidirectional Computer Interface (BCI) is installed with the VITEK® 2 Systems software. BCI requires that you configure additional settings in the system software.

The **BCI Configuration** menus must be set up according to the connection protocol developed with your Laboratory Information System (LIS) computer service company.

To perform this connection you must call bioMérieux. The technical characteristics of the BCI are available from the bioMérieux Global Customer Support.

CAUTION: Configuration and starting of the BCI (Bidirectional Computer Interface) equipment and software required for the bioMérieux computer system or for your laboratory information system (LIS) must be performed by qualified personnel authorized to do so. Any unauthorized modification may lead to incorrect operation.

View and Maintain Connection Status

Note: *BCI must be configured from within the interface connection before you can maintain the system software. For details, see* *BCI Configuration Settings on page 12-25**.*

BCI Status view contains the following information about the user-defined connections:

- **Supervision:** Provides the global status on each link.
- **Transaction Log:** Displays the history of transactions and allows the user to see what isolates have been uploaded over time.
- **Link Operation:** Provides detailed upload and download activity on a particular connection.
- **Link Configuration:** Displays the parameter screen for each connection.
- **Tools:** Allows you to print, restore, and save a configuration.

Note: *To maintain BCI status, you must be a Supervisor or an Administrator of the system software.*

Once BCI is configured, you can click **View BCI Status** to view the current connection status for the defined interfaces.

1) To access the BCI Status screen, click on the **BCI Alarm and Status** icon located at the bottom-left of any screen within the system software.

Figure 12-1: BCI Connection Status

2) From within the BCI Status and Alarm view, click **View BCI Status**.

3) The software prompts you to enter your *User Name* and *Password*.

4) The BCI Status window appears.

5) Navigate to one of the following options to maintain the interface connections:

- Supervision, see Supervision on page 12-4.
- Transaction Log, see Transaction Log on page 12-7.
- Link Operation, see Link Operation on page 12-9.
- Link Configuration, see Link Configuration on page 12-14.
- Tools, see Tools on page 12-20.

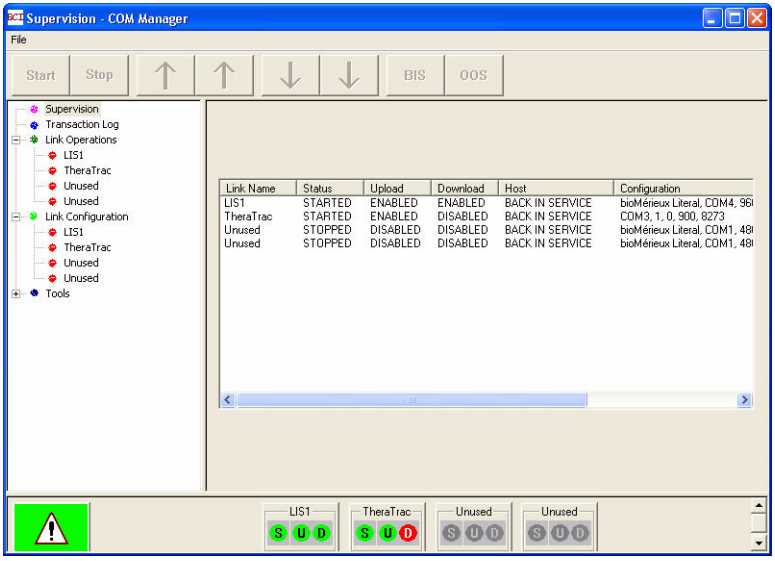

Figure 12-2: BCI Status

Supervision

Supervision is the first link in the Navigation tree, it allows you to see a global status on each link.

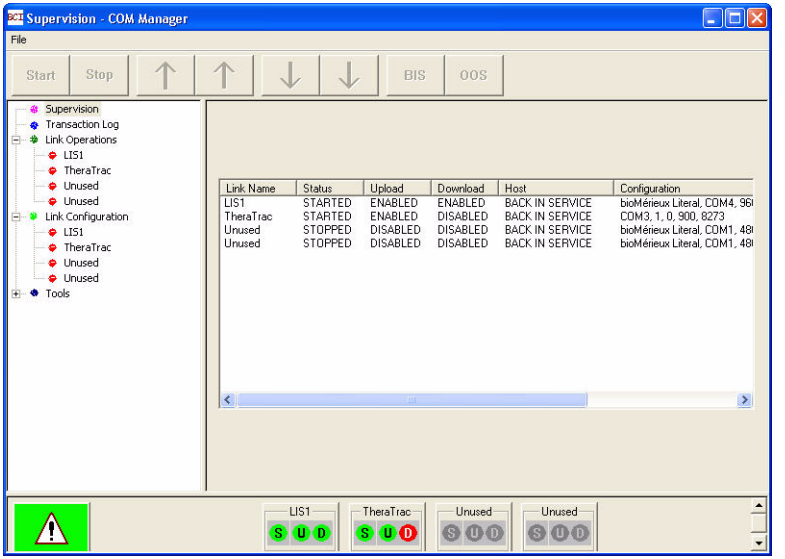

Figure 12-3: Supervision

For each interface name the following global status information is displayed:

- **Link Name:** This is the user-defined name given to the connections interface.
- **Status:** Displays the connection status for the user defined links; it displays whether they are Started or Stopped.

  STARTED: Indicates that BCI is running and therefore allows communication with the selected link.

  STOPPED: Indicates that BCI is not running and communication with the selected link is not possible.

- **Upload:** Displays whether the Upload connection is enabled or disabled to send data from the system workstation to the LIS.

  ENABLED: BCI allows the applications to send to the host.

  DISABLED: BCI does not allow the applications to send to the host.

- **Download:** Displays whether the Download connection is enabled or disabled to receive data from the LIS.

  ENABLED: BCI processes the message sessions transmitted by the LIS.

  DISABLED: BCI does not process the message sessions transmitted by the LIS.

- **Host:** Displays the status of the external data management computer (LIS).

  IN SERVICE: The LIS is available to receive results.

  OUT OF SERVICE: The LIS is not available to receive results.

  NO RESPONSE: The LIS does not respond when BCI tries to open a session by sending <ENQ>.

  BACK IN SERVICE: The LIS is available again to receive results.

- **Configuration:** The protocol used and the physical parameter setting of the link are displayed on this screen.

  The following parameters are available: protocol, port, baud rate, data bits, parity, stop bits and hardware flow control for a serial link port.

Note: *A laboratory technologist can start or stop the interface connections at any time.*

Status of the Connection

The status of each of the interface connections appears at the bottom of the Link Configuration screen. This allows you to see the status of the three following operations for each interface connection:

- **S: Start/Stop**

  Green = Connection started

  Red = Connection halted.

- **U: Upload**

  Green = Transmission of results to an external data management computer is enabled.

  Red = Transmission of results to an external data management computer is disabled.

- **D: Download**

  Green = Reception of results from mainframe is enabled.

  Red = Reception of results from mainframe is disabled.

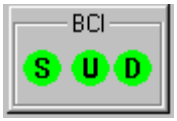

Figure 12-4: BCI Connection Status

Alarm Connection

The following alarm states may appear:

Green = No alarm.

Red = Alarm!

Figure 12-5: Alarm Connection

When the alarm state is red, click the **Alarm** icon to open the Event Viewer window. For further information call bioMérieux.

Unused Connection

If there is an unused connection, all indicator lights appear dark gray.

Figure 12-6: Unused Connection

Transaction Log

The transaction log displays the history of transactions, and allows the user to see what isolates have been uploaded or downloaded over time. To access the transaction log, select **Transaction Log** from the navigation tree.

IMPORTANT: ***The connection must be started and uploads enabled in order for transactions to appear in the BCI Transaction Log. If BCI is stopped and/or uploads are disabled, the VITEK® 2 Systems software will store the transactions until the port is started and uploads are enabled. This means both Automatic Transfer and Send to LIS (user initiated transfer) uploads are queued in the system software until the port is started and uploads are enabled. If the port is started but downloads are disabled, any packet received from the LIS will be discarded.***

When the window first appears the transaction log is empty. You must first apply a filter to see results.

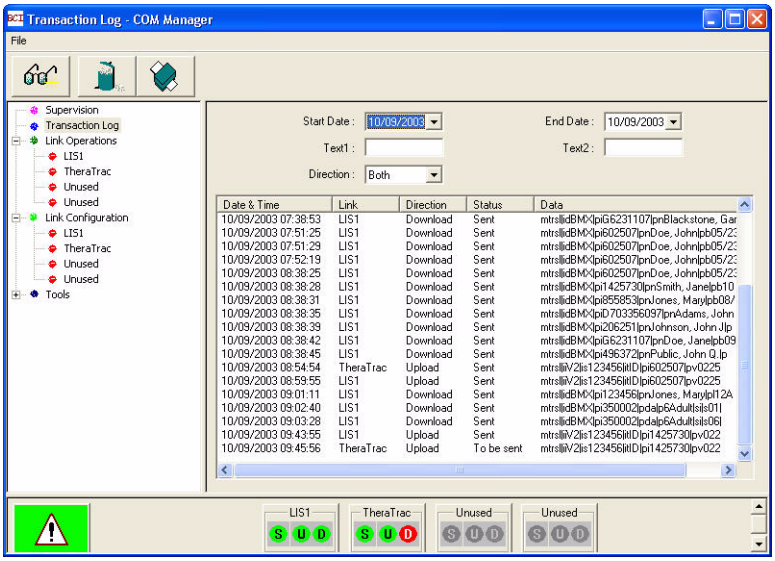

Figure 12-7: Transaction Log

Search Transaction Log

To search the transaction log, you have the following options:

1) Select a *Start date* and an *End date*.

2) Type in any *Text* in the two text fields to help you identify the history log that you want to find.

3) Choose the direction of the transaction by selecting either **Reception/ Download, Transmission/Upload** or **Both** from the **Direction** drop-down list.

4) Click **Search** to update the current window.

Figure 12-8: Search Button

5) This option allows viewing of the communications sessions that have taken place by providing the following information:

- **Date & time:** Date and time of the transaction.
- **Link:** Name of the link with which the transaction occurred.
- **Direction:** Nature of the transaction (upload or download)
- **Status:** Status of the transaction (sent, to be sent, etc.)
- **Data:** Content of the transaction (reminder of the message received or sent)

Deleting Transaction Log Messages

Note: *To delete uploaded messages, you need to log in as a supervisor.*

To delete transaction log information follow these steps:

1) Select the messages you want to delete.

2) Click on the **Date & Time** corresponding to the message you want to delete.

3) You can select several messages at a time:

- Select the first message, press **Shift** and select the last message to delete,
  or
- Press **Ctrl** and select in succession the messages you want to delete.

4) Click the **Delete** button. The corresponding messages disappear.

Figure 12-9: Delete Button

Note: *The transaction entries selected for deletion are deleted regardless of status.*

Printing Uploaded Messages

To print uploaded messages:

1) Select the message that you want to print.

2) Click on the **Print** button.

To print one or more messages at a time:

3) You can select several messages at a time by:

- Selecting the first message, pressing **Shift** and selecting the last message to be printed,
  or
- Pressing **Ctrl** and selecting in succession the messages you want to print.

4) Click the **Print** button.

Figure 12-10: Print Button

Note: *After each print out, the screen must be refreshed. To do so, you have to perform a new search.*

5) Click the **Search** button.

Figure 12-11: Search Button

Link Operation

This menu gives access to four possible interface communication links. These links are configured from the interface connection.

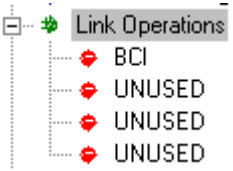

Figure 12-12: Links

Select the link you want to view and maintain. The window for the selected link is displayed:

Figure 12-13: BCI Link

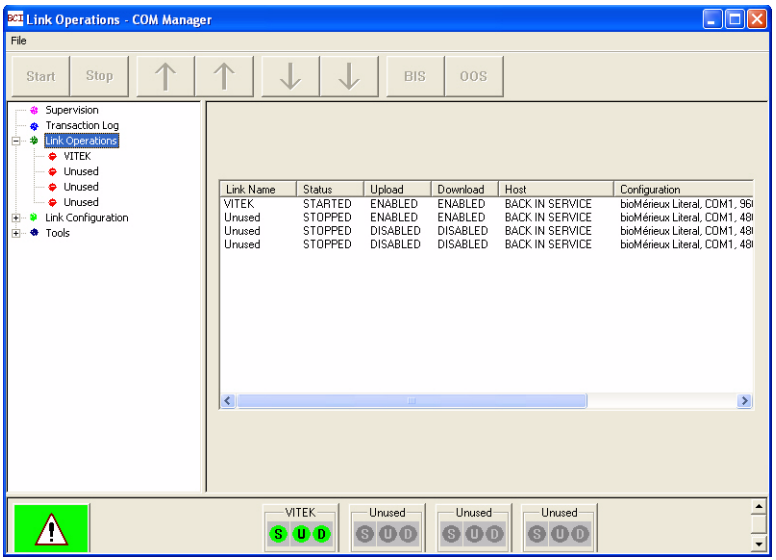

Figure 12-14: Link Operations Window

Start/Stop the Connection

At any time, the laboratory technologist can enable or disable the selected interface connection.

When the **Start** button appears selected, the connection has started.

Select **Stop** to halt the connection. The indicator light **S** changes to red.

Figure 12-15: Start/Stop Connection

Transmission of Results (Upload)

When the green/left arrow is selected, the transmission of results to the external data management computer is enabled, the corresponding status indicator light **U** is green.

Select the red arrow to disable transmission, and the status indicator **U** changes to red.

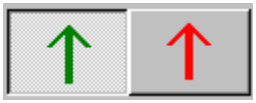

Figure 12-16: Transmission Buttons

Reception of Data (Download)

When the green arrow is selected, the reception of data from the external data management computer is enabled and the corresponding status indicator light **D** is green.

Select the red arrow to disable the reception of data (patient and specimen information) and the status indicator **D** changes to red.

Figure 12-17: Download Button

Results on Hold (Back in Service/Out of Service)

CAUTION: Use of BIS and OOS functions is typically automated by the LIS. Refer to the LIS connection protocol, or for further information contact the bioMérieux Global Customer Support.

The BIS button (green) appears pressed down when the external data management computer is receiving upload from the bioMérieux computer.

Figure 12-18: BIS

The OOS button (red) appears pressed down when results are not being uploaded to the external data management computer. The bioMérieux computer will not attempt to upload to an external data management computer in this state.

Figure 12-19: OOS

View Link History

When you select a link, **History** is selected by default. The selected link operation submenu displays the history of the communications tracking data.

The following transmission information displays:

- Number of the day in the year (this is listed first as the Julian date of the year)
- HH:MM:SS (hour:minute:second)
- Protocol characters (for example, <ENQ>)
- Data transmitted or received

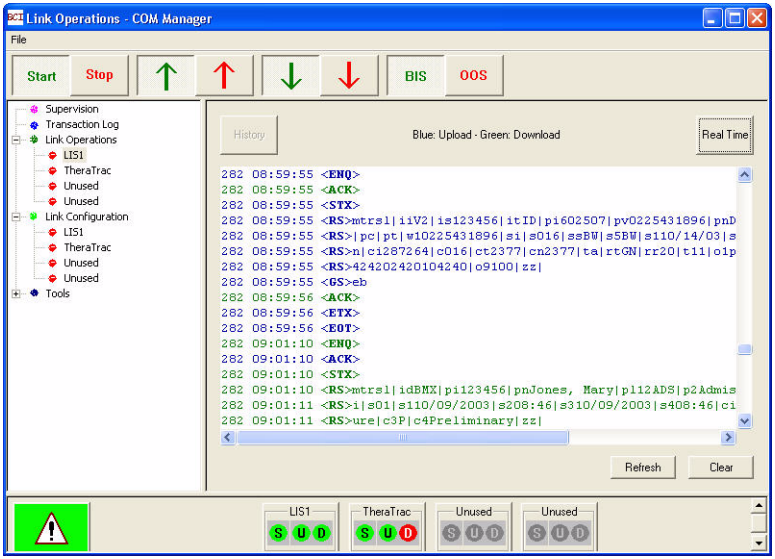

Figure 12-20: Link Operations-Submenu History

Viewing Real-time Interface Connection

To allow the user to view communication packets in real-time to troubleshoot an interface connection:

1) Select a link to view the connection packets.

2) The current connection workspace displays, and the following information appears:

- Protocol characters (for example, <ENQ>, <ACK>, etc.) and the related packet of information, including the field code (for example, pn, etc.) and delimiter (for example | etc.)

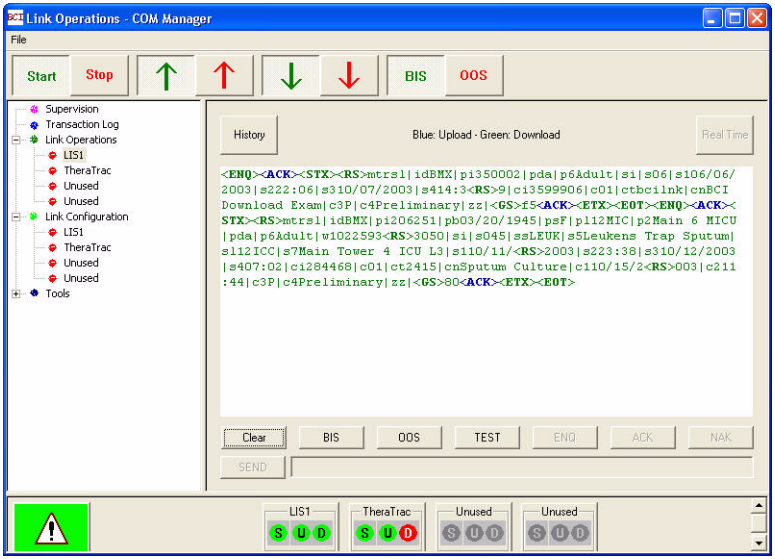

Figure 12-21: Link Operations-Submenu Real-Time

Note: *As additional transactions fill the window, a scroll bar appears allowing you to view additional transmissions.*

3) Click **Clear** to clear the contents of the window.

Note: *Any problems that occur are reflected by the **Alarm** icon.*

4) Click **Real Time**, then **Test**.

5) In the Open screen, change the **Files of Type** option to **(*.txt)**.

6) Select **test pattern**, then click **Open**. The test pattern displays.

Note: *If you do not see the test pattern, navigate to* **D:\Program Files\VITEK 2 Compact** *and select the test pattern text file: TestPattern***.**

Note: *Click **BIS** to send a Back in Service message to the LIS and click **OOS** to send an Out of Service message to the LIS.*

Link Configuration

The Link Configuration screen allows you to enter parameters for each link.

Note: *It is possible to print the BCI configuration using the Tools options in the navigation tree. For details, see* *Tools on page 12-20**.*

To access the Link Configuration screen, follow these steps:

1) From within the Supervision view, double-click **Link Configuration** in the navigation tree.

2) Click on one of the links to display the work window.

Note: *To access the Link Configuration menu, you must log in as a supervisor.*

3) The Link Configuration COM Manager window displays.

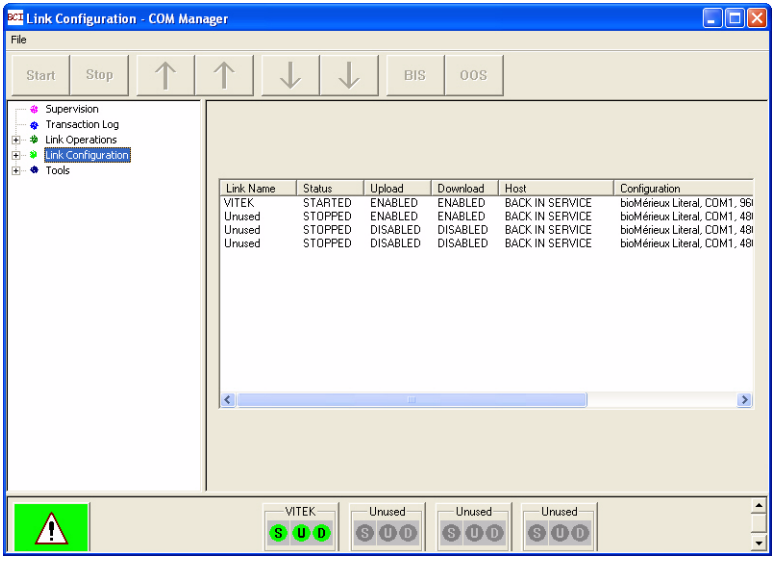

Figure 12-22: Link Configuration

Note: *These parameters must be set taking into account the characteristics of the connection protocol developed by your computer company. For further information, call bioMérieux Global Customer Support.*

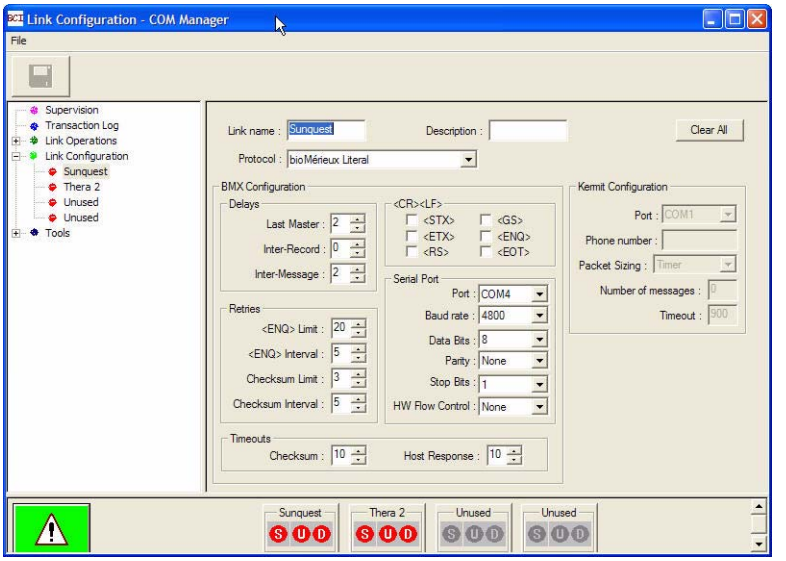

Figure 12-23: Link Configuration Submenu

4) Click on **Link Configuration** to return to the main **Link Configuration - COM Manager** menu.

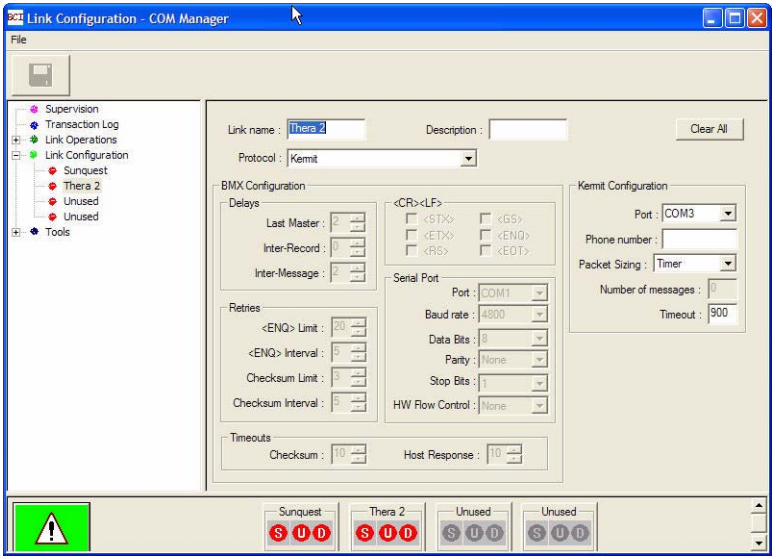

Figure 12-24: Link Configuration Submenu

The following table describes each configuration setting and gives the possible values and default values for each one:

Table 12-1: Configuration Parameters

Parameters	Description	Possible Values	Default
Name of the link	Name of the LIS. **Note**: You must enter a name for the LIS, and you cannot use a name that is already in use. **Important: Do not change the port name to Unused. You must stop the port and reset it in BCI to revert the port to Unused.**	Any name is valid except the default value. Limit of 32 characters.	Unused
Description	Free entry	Free entry. Limit of 32 characters.	Blank
Protocol	Choose between the following: • **Literal:** This is a proprietary data transfer protocol developed by bioMérieux used to transfer information between computers. • **Literal (Alternate):** Same as Literal except all messages are dealt with after reception of the <ETX> character. • **Kermit:** A file transfer and terminal emulation program developed to transfer asynchronous files between computers. • **Manual:** This is a tool that helps set up the connection with the LIS.	• bioMérieux Literal • bioMérieux Literal (alternate) • Kermit • Manual	bioMérieux Literal
BMX configuration			
Delays:			
Last Master	Amount of time BCI waits before starting another session. It sends an <ENQ> when it was master of the last session.	0 to 99	2
Inter-Record	Delay between transmission of 2 recordings by BCI.	0 to 99	0
Inter-Message	Delay between transmission of 2 messages (<STX>...<ETX>) by BCI.	0 to 99	2

Table 12-1: Configuration Parameters

Parameters	Description	Possible Values	Default
Retries:			
<ENQ>Limit	Number of times BCI tries to open a session. When this limit is reached, BCI records an error message and places the data in a waiting list. If the LIS responds, BCI empties the waiting list and records a new message saying that the LIS responded.	0 to 99	20
<ENQ>Interval	Amount of time BCI waits before the next transmission of an <ENQ> following a no response or reception of a <NACK>.	0 to 99	5
Checksum Limit	BCI will retransmit the entire packet if it receives a <NACK> for the transmitted checksum, or if the checksum Timeout expires. This limit is the maximum number of packet retransmissions by BCI to try to obtain acquittal of the checksum. When the limit is reached, BCI records an error message and destroys the packet.	0 to 99	3
Checksum Interval	Amount of time BCI waits before retransmitting the packet following reception of a <NACK> in response to the checksum or if no response is received.	0 to 99	5
Timeouts:			
Checksum Timeout	Amount of time BCI waits before retransmitting the packet following reception of a <NACK> in response to the checksum or if no response is received.	0 to 99	3
Host Response Timeout	Time allowed by BCI for the host to respond when BCI is expecting data when a session has been opened by the LIS. When this time expires, BCI closes the session by sending an <EOT>. BCI also records an error message.	0 to 99	10

Table 12-1: Configuration Parameters

Parameters	Description	Possible Values	Default
<CR><LF> Note: If these are enabled for uploads they will also be required for download packets.			
<STX>	Start of transmission.	enabled/disabled	disabled
<ETX>	End of transmission.	enabled/disabled	disabled
<RS>	Record Separator	enabled/disabled	disabled
<GS>	Checksum	enabled/disabled	disabled
<ENQ>	Line Request Character	enabled/disabled	disabled
<EOT>	End of transmission.	enabled/disabled	disabled
Serial Port:			
Port	Serial port used by the link.	Between COM1 and COM4	COM1
Baud rate	Transfer speed.	Between 110 and 256000 baud	4800
Data bits	Number of bits per character.	Between 4 and 8 bits	8
Parity	Refers to an error-checking method used by computers to determine the integrity of the information transmitted over a communication line. If the receiving computer detects a deviation in the parity bit, then it signals the sending computer that there may be a problem with data integrity.	Choose between: None Even Odd Forced to 1 Forced to 0	None
Stop bits	Used by computers to indicate the end of each character as it is transmitted over a communication line. This allows the receiving computer to recognize the end of each character.	Choose between 1, 1.5, and 2	1

Table 12-1: Configuration Parameters

Parameters	Description	Possible Values	Default
HW Flow	Hardware handshaking: define as required and the same as the cable.	None DTR/DSR RTS/CTS Full	None

Tools

Before opening or printing a file, you must save it.

1) Select **Save Configuration**.

2) Choose a file name and determine its location on your computer.

Note: *To access the **Open Configuration** and **Save Configuration** options in the **Tools** menu, you must log in as a supervisor.*

If you log in as a laboratory technologist, you will only be able to print the configuration.

3) Double-click **Tools.**

4) The Tools submenu is displayed:

- **Open Configuration:** Enables you to load connection parameters.
- **Save Configuration:** Enables you to save connection parameters. You will be prompted to enter a file name.
- **Print Configuration:** Enables you to print and archive connection parameters.

BCI Alarm Status Icons

OK: The icon with the green square means the connection with external data management system is okay. Click this icon to see the connection status.

Figure 12-25: Connection OK Status

Warning: The icon with the orange triangle indicates a problem with the data management system. Click this icon to see the status of the connection and a description of the warning.

Figure 12-26: Connection Warning Status

Error: The icon with the red circle indicates an error in the BCI connection. Click this icon to see a description of the error condition.

Figure 12-27: Connection Error Status

View and Maintain BCI Status and Alarms

Viewing and maintaining BCI status and alarms allows a Laboratory Technologist or Laboratory Supervisor to determine the current state of system software interface connections. BCI Status and Alarms can be viewed from any screen within the system software.

BCI Alarm history allows you to view the current status of connections, and execute some troubleshooting techniques. If an alarm condition is detected, clicking on the status indicator will display the BCI alarm history window.

At any time, you can select the **BCI Status** icon to view details about all defined connections.

1) To view BCI status and alarms, click the **BCI status** icon at the bottom of the screen.

Figure 12-28: BCI Status

2) The BCI Alarm Status and History window appears.

Note: *If there is a current alarm, the Current BCI Alarm tab appears in front. If there are no current alarms, the BCI Alarm History tab appears in front.*

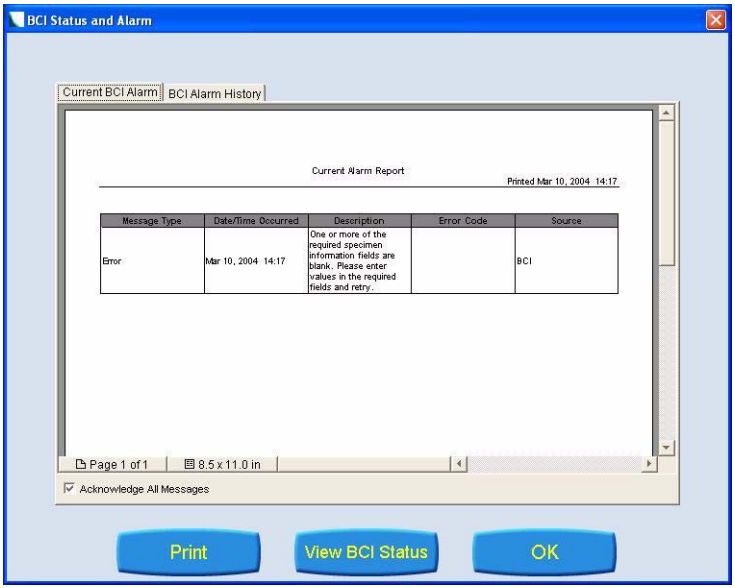

Figure 12-29: Current BCI Alarms

3) Click on the one of the tabs to view details about the defined connections.

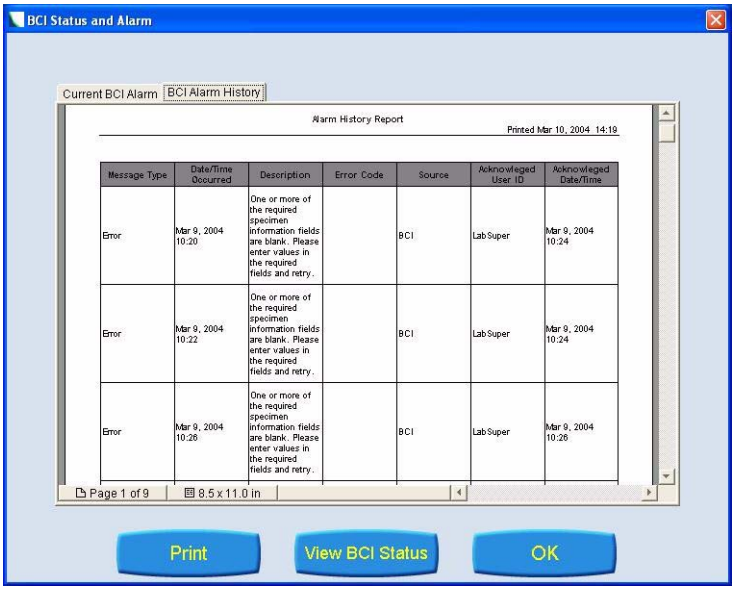
BCI Status and Alarm
Current BCI Alarm
BCI Alarm History
Alarm History Report
Printed Mar 10, 2004 14:19
Message Type
Date/Time Occurred
Description
Error Code
Source
Acknowleged User ID
Acknowleged Date/Time
Error
Mar 9, 2004 10:20
One or more of the required specimen information fields are blank. Please enter values in the required fields and retry.
BCI
Lab Super
Mar 9, 2004 10:24
Error
Mar 9, 2004 10:22
One or more of the required specimen information fields are blank. Please enter values in the required fields and retry.
BCI
Lab Super
Mar 9, 2004 10:24
Error
Mar 9, 2004 10:26
One or more of the required specimen information fields are blank. Please enter values in the required fields and retry.
BCI
Lab Super
Mar 9, 2004 10:26
Page 1 of 9
8.5 x 11.0 in
Print
View BCI Status
OK

Figure 12-30: BCI Alarm History

Current BCI Alarm Report

The Current BCI Alarm Report displays the current BCI alarms to help you troubleshoot the connection.

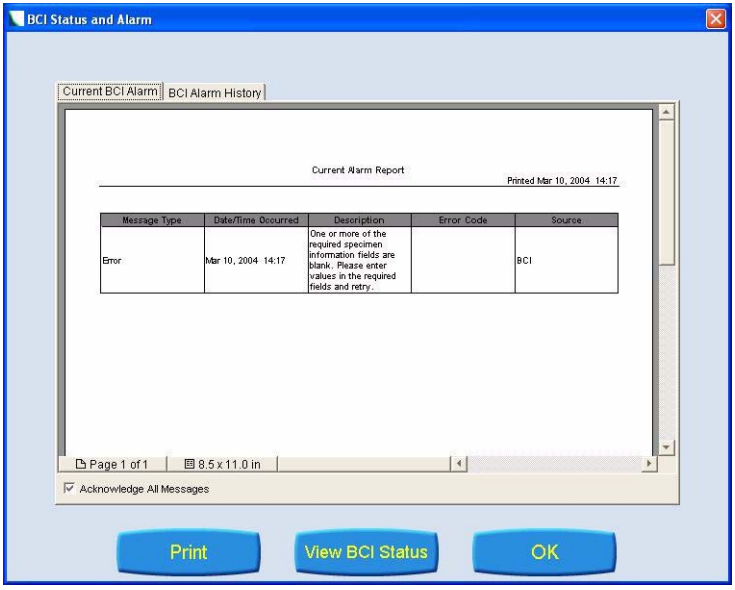

Figure 12-31: Current BCI Alarms

BCI Alarm History Report

The BCI Alarm History Report displays the BCI alarm history to help you troubleshoot the connections status.

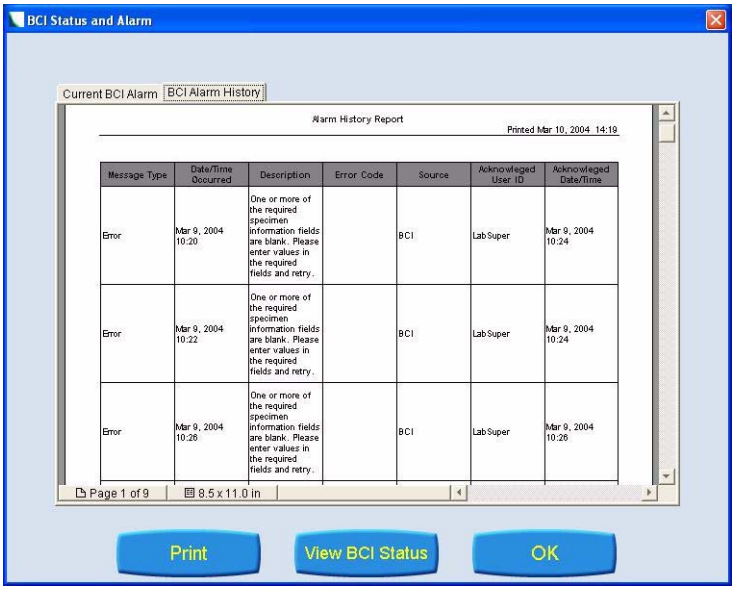

Figure 12-32: BCI Alarm History

BCI Configuration Settings

From the Main view, follow these steps to Configure BCI:

1) Click **Configuration** and select **BCI Configuration** from the drop-down list.

2) The General BCI Configuration view appears.

3) Select the desired connection interface.

Note: *The connection must be previously defined in Link Configuration.*

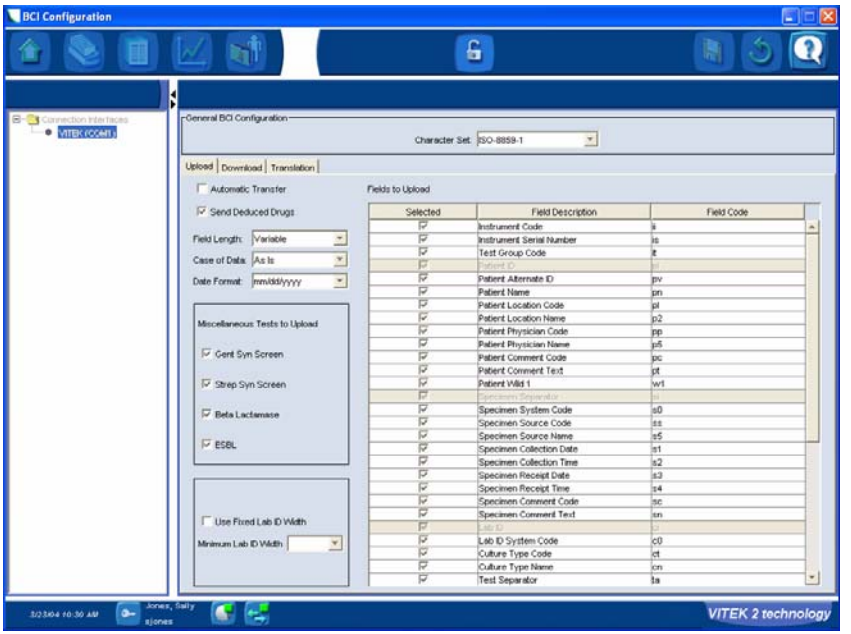

Figure 12-33: BCI Configuration View

4) If you are a supervisor, you can unlock this view and make any necessary configuration changes.

Note: *A Kermit port will not have the COM port listed in parenthesis.*

Note: *When you select* **Send to LIS** *in View and Maintain Isolate Results, the data is sent to all the ports listed in the connection interfaces.*

When creating a new port, exit the screen by clicking on another view (for example, Main view) and then return to the BCI Config window to see the new port.

General BCI Configuration Settings

Character Set: Select the Character Set from the drop-down list if the system software and the external data management system communicate using a different character set. Character sets include:

- ISO-8859-1 (Default)
- VTF-8
- Shift-JIS

BCI Upload Tab

This tab allows you to set up and define information regarding which fields you want to send to the LIS for the selected connection.

TABLE 12-2: BCI UPLOAD TAB SETTINGS

BCI Configuration Setting	Description	Default Value
Automatic Transfer	Transfer results as soon as they are complete and final.	Disabled
Send Deduced Drugs	If enabled, deduced drugs are included in the BCI packet.	Enabled
Field Length	The character length for the fields sent to the LIS.	Variable
Case of Data	Sent data is in upper or lower case format.	As Is
Date Format	The format in which the date is sent to the LIS.	mm/dd/yyyy
Miscellaneous Tests to Upload	Special tests that do not have typical MIC Interpretation results.	Enabled
Use Fixed Lab ID Width	Use a predetermined width for the Lab ID field.	Disabled
Minimum Lab ID Width	The minimum width allowed for the Lab ID field.	Disabled
Fields to Upload	The fields to be sent to the LIS.	All Selected

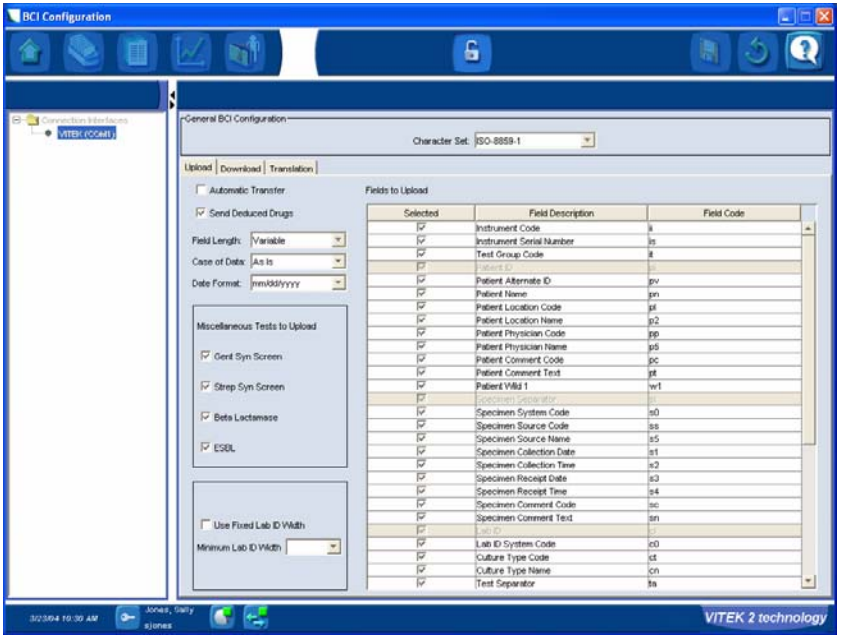

Figure 12-34: BCI Configuration View (Upload Tab)

BCI Download Tab

This tab allows you to choose fields received from the LIS. The following options are available:

- **Fields to Download:** The required fields are not available for selection. The optional fields are enabled by default.
- **Update Duplicate Demographics:** When specific patient information has already been downloaded and additional information is available, you can chose to update the patient information with the most recent information. The default is **Enabled**.

- **Date Format:** From the drop-down list, select the date format that you will receive from the data management system. Default is **mm/dd/yyyy**.

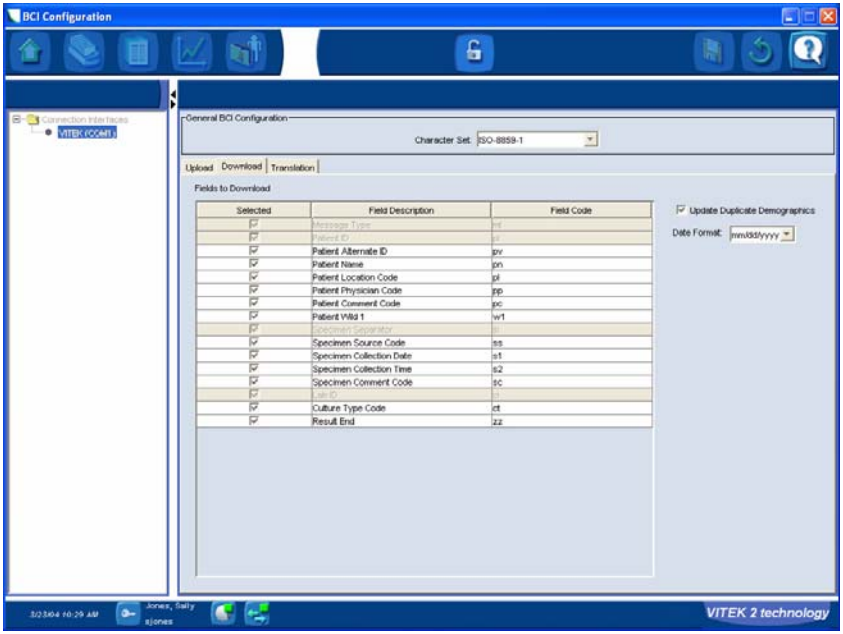

Figure 12-35: BCI Download Tab

BCI Translation Tab

This tab allows you to set up how you want to map field codes for organisms and antibiotics. To use this tab, follow these steps:

1) Select **Organism** or **Antibiotic** from the drop-down list.

2) Scroll down the list of antibiotics or organisms and type any codes into the host code column that you need to map to your external data management system.

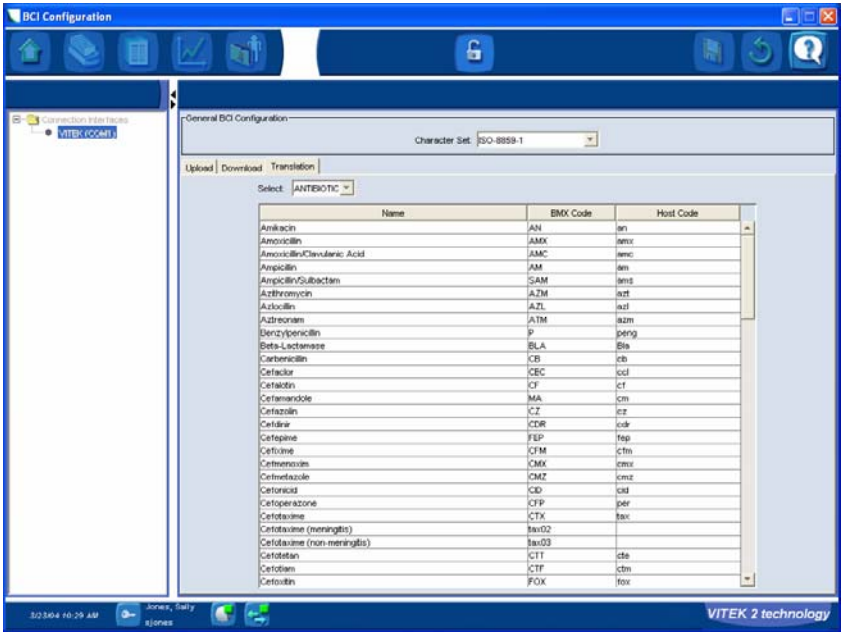

Figure 12-36: BCI Translation Tab

SYSTEM UTILITIES 13

About This Chapter

This chapter describes the following system utilities: Create and Maintain User Security, Create and Maintain AST Card Definitions, View and Maintain Instrument Status, Archive, Search Isolate History (Audit Trail), and Export Data to a CD.

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Create and Maintain User and Security Settings

To begin using the VITEK® 2 Systems software, you need to set up the computer to allow users to log in to the system software.

The VITEK® 2 Systems software uses the *User ID*, *User Name*, and *Password* created in Windows XP® to authenticate users. You must enable user accounts with an active *password* from within Windows XP® to allow users log in to VITEK® 2 Systems software.

Note: *It is recommended that you use the specified user groups for increased security and the user information in the Audit History.*

To create new user groups, you must log in to Windows XP® as an Administrator. You will need to:

- Create User Accounts/IDs
- Add User Accounts/IDs to the User Groups

Note: *For details, please refer to the Windows XP® online help.*

Initial User Accounts

There are four initial user accounts already established upon installation. Each user account maintains access to certain functionality based on their group membership. The following tables specify the user account and user group information provided with VITEK® 2 System.

Table 13-1: User Group Descriptions

Group	Comment
Administrators	Windows XP® group with full access to the operating system.
Users	Windows XP® group with limited access to the operating system
Supervisors	VITEK® 2 System group: • Log in to VITEK® 2 Systems Software • Restore database backups • Configure system software • Approve lab reports • Search isolate and application audit trails. • View previous versions of lab reports.

Table 13-1: User Group Descriptions

Group	Comment
Laboratory Technologists	VITEK® 2 System group: • Log in to VITEK® 2 Systems software • Perform daily activities supported by the VITEK® 2 Systems software.

Table 13-2: Default User Accounts

User ID	Password	Windows XP® Access	VITEK® 2 Systems Software Access	Group Membership
Admin	bmx_admin	Full	None	Administrators
LabAdmin	labadmin	Full	Full	Administrators and Supervisors
LabSuper	labsuper	Limited	Full	Users and Supervisors
LabTech	labtech	Limited	Limited	Users and Laboratory Technologists

Note: *For details on creating user accounts and adding users to groups, please refer to the operating system user documentation provided with Windows XP®.*

Note: *It is possible to log into Windows XP® as one user and simultaneously log in to the VITEK® 2 Systems software as a different user. Depending on your laboratory security policies, you may want to leave a default user logged in to Windows XP® at all times and only require your personnel to log in to the VITEK® 2 Systems software application. For added security you may want to require your personnel to log in and out of both the application and Windows XP® using their own account.*

Creating User Accounts

To create user accounts, log in to Windows XP® as an Administrator.

Note: *If you are already logged into an account without administrators membership, you will need to log out.*

Example:
User Name: LabAdmin
Password: labadmin

1) Right-click on the **Computer** icon located in the upper left corner of the desktop, and select **Manage** to open the Computer Management window.

2) Under **System Tools,** expand **Local Users and Groups.**

3) Right-click on **Users** and choose **New User**. The New User window appears.

4) Enter the *User Name*. (For example, LabTech1)

5) Enter the *Full Name*, as you want the user's name to appear within the VITEK® 2 Systems software.

Note: *bioMérieux recommends that you enter last name, first name.*

6) Enter an optional description.

7) Enter the user's *password*. By default, the password must contain a minimum of six alphanumeric characters.

8) Enter the *password* again to confirm your password.

9) Select the password options that best meet your laboratory's needs.

Note: *If you do not select **Password never expires**, the user must periodically log in to Windows XP® and update their password. The VITEK® 2 Systems software will not provide a warning if the password is about to expire.*

Note: *If you select **User must change password as next logon**, the user will not be able to access the VITEK® 2 Systems software until after the password has been changed by logging in to Windows XP®.*

10) Click **Create** and click **Close**.

11) Add the user to the appropriate User Group.

Adding User IDs to User Groups

To add User IDs to User Groups, log in to Windows XP® as an Administrator.

Note: *If you are already logged on to an account without administrator's membership, you will need to log off.*

Example:
User Name: LabAdmin
Password: labadmin

1) Right-click on the **Computer** icon located in the upper left corner of the desktop, and select **Manage** to open the Computer Management window.

2) From the Computer Management main window, click **System Tools** > **Local Users and Groups** > **Users**.

3) From the list of users shown on the right, right-click on one of the **User ID**s and choose **Properties.**

4) From the User Properties window, click on the Member Of tab, then click on the **Add** icon.

5) From the Select Groups window at the cursor type the name of the group to which you want the user to belong (for example, Laboratory Technologists, Supervisors, or Administrators)

6) After entering the name of the group, click **OK** to add the user.

7) Click **Apply** and **OK**.

8) You have successfully added the user to the user group. The user should now be able to log in to the system.

Creating AST Card Definitions

With each new AST card, you need to define a custom AST card to the system software and instrument. If the AST card type was not previously defined, you need to create the AST card definition.

To create a new AST card definition:

1) From the Main view, select **Utility View** > **Maintain AST Card Definitions**.

2) The system software displays a list of current AST card definitions, sorted by card type.

3) To add a new AST card definition to the system, select **Enter New AST Card Type**.

Figure 13-1: Enter New AST Card Type

4) In the **Package Insert Bar Code** field, enter the bar code from the package insert. You can enter it manually or by using the bar code reader.

5) After each bar code is entered, the system software validates it and displays the new card information.

6) The following information appears:

- Bar code line number(s)
- Card type
- Card name
- User ID
- Date created
- A list of antibiotics on the card

Note: *If a card cannot be validated, the system software prompts you to re-enter or cancel the card definition.*

7) When you have finished entering the bar codes, you will need to confirm that the displayed list of all antibiotics from the bar codes matches the antibiotics listed in the package insert by selecting the check box **Antibiotics list matches package insert at the bottom of the workspace area**.

8) Click **Save** to update the new information.

9) Upon confirmation, the new card definition is added to the installation's card definitions and the card definition is sent to the instrument.

10) All necessary information has now been entered to run and analyze tests using the new AST card.

Deleting a Card Definition

When you are viewing and maintaining the card type from the displayed list, you may also want to delete some card definitions:

1) From the Maintain AST Card Definition view select the AST Card definitions that you want to delete from the system.

2) Select the definition that you want to delete, and click **Delete AST Card Type**.

Figure 13-2: Delete AST Card Type

3) If any of the selected cards are currently in the active workspace, a message appears letting you know that the card definition cannot be deleted because the card type is actively in use.

4) If the card is not in use, you will be asked to confirm deleting the card definition.

5) When you confirm deleting this card definition, the card definition is deleted from the workspace.

Maintain AST Card Definitions

Note: *When entering a new card type, you should have a copy of the package insert that contains the necessary bar codes to create the definition.*

The order of the bar codes on the insert is encoded so that the system software will be able to determine which is the first bar code to be entered.

The first bar code contains information about the number of antibiotics contained on the card. Based on this information, the system software can determine the number of bar codes that must be entered to complete the card definition.

Bar codes can be scanned or entered manually. Each bar code has a checksum or another means of validating it after data entry.

Card definitions cannot be updated; if they need to be changed, the system deletes the existing card definition and replaces it with a new one that includes the changes.

You can create and maintain AST card definitions regardless of whether you are operating in Clinical or Industry mode. To maintain AST card definitions:

1) From the Main view, select **Utility view** > **Maintain AST Card Definitions**.

2) A list of current AST card definitions appears sorted by Card Type. The information displayed includes:

- Card Type
- Card Name
- User ID (who created the definition)
- Date Created (when the cards was defined)

3) The currently selected card definition appears in the workspace area.

Figure 13-3: Maintain AST Card Definitions

Archive Isolate Reports and Isolate Audit Trail

Note: *21 CFR 11 must be enabled to create an Archive CD.*

Archiving Isolates

The Archive includes:

- Isolate Results

- QC Results
- Isolate Audit Trail
- Application Audit Trail

The archive workspace is a repository for older tests that have been deleted from the Active Workspace area. The time of archiving is determined by application configuration; bioMérieux recommends seven days.

If 21 CFR 11 is enabled, all isolates (including product and QC isolates) must be archived. If 21 CFR 11 is enabled, all deleted isolates should be included in the archive.

Archive Isolates

Only isolates that meet certain criteria can be archived to a CD. The following list contains types of isolates eligible for archive:

Table 13-3: Isolates Eligible For Archive

Type of Isolates	Isolate Status
Test Isolates	• Final • Not Qualified • Reviewed • Approved • Aged from Active Workspace
QC Isolates	• Final • Not Qualified • Reviewed • Approved • Aged from Active Workspace
Deleted Isolates	• 21 CFR 11 Enabled • Aged from Active Workspace

What Happens to Deleted Isolates?

When 21 CFR 11 is enabled, deleted isolates are not deleted, they are flagged as Inactive and moved to the inactive workspace. When the user creates an archive CD, deleted isolates are copied with other isolates and QC to the archive CD.

Archiving Isolates to a CD

Note: *It is recommended that you use read only media (for example, CD-R) for archiving isolate reports and audit history to prevent overwriting the archive information.*

To archive isolates:

1) From the Main view, select **Utilities view** > **Archive and View Archived Reports**.

Figure 13-4: Archive Isolate Reports and Audit Information

2) Click the **Archive Isolate Reports and Audit History** icon.

A prompt to enter a blank CD will display.

3) Insert a blank CD and wait for the green light to disappear.

4) Select **Yes** to continue.

Note: *If a CD is not already inserted, a message appears asking you to insert a blank CD.*

5) The Isolate Reports are copied onto the archive CD.

6) The following information is archived to the CD:

- Current Isolate Report
- Previous Isolate Report Versions (if 21 CFR 11 is enabled)
- Isolate Audit (entire audit since last archive)
- Application Audit

7) If there are too many Isolate Reports for one CD or the CD is full, a message appears.

8) When archive is complete, a reference number is automatically assigned to the CD. A supervisor can use this reference number to locate the isolate reports for inspection.

9) When the archive is complete an index is created on the CD to allow the Supervisor to easily find specific isolate reports.

Note: *Be sure to label the archive CD to easily find specific archived isolate reports.*

Too Many Isolate Reports for One CD

If there are too many Isolate Reports for one CD, a message appears letting you know that there is not enough space on the CD for all of the Isolate Reports. The system software displays an approximate number of CD-Rs needed to complete archive.

When the first CD is full, the system software will prompt you to remove the CD and insert another one until archive is complete.

Viewing and Searching Archived Isolate Reports

As a Supervisor you can view the following items:

- Archived Isolate Reports
- Archived Isolate Audit
- Archived Application Audit
- Previous Version of Isolate Reports

Note: *Only a Supervisor can view archived isolate reports from an archive CD.*

1) From within the Main view, select **Utilities view** > **Archive and View Archived Reports** to view the most recent version of the Isolate Reports.

2) Archived Application Audit can be viewed using the Search Audit Trail function.

3) To find a specific Isolate report, enter one or more of the following search criteria:

- Laboratory Identification Number
- Isolate Number
- QC Reference ID (If the Laboratory Identification Number or Isolate Number is entered, entering a QC Reference ID is optional).
- Date Range including Start Date and End Date

4) To view the archived isolates on the system, select Search Online Catalog and click **Search**.

5) To view the archived Isolates from the Archived CD, select Search CD and click **Search**.

- Insert an archive CD.

Note: *If a CD is not already inserted, a message appears asking you to insert an archive CD.*

Note: *You may use an asterisk as a wild card when entering search criteria.*

6) A list of archived isolates meeting the specified search criteria is displayed.

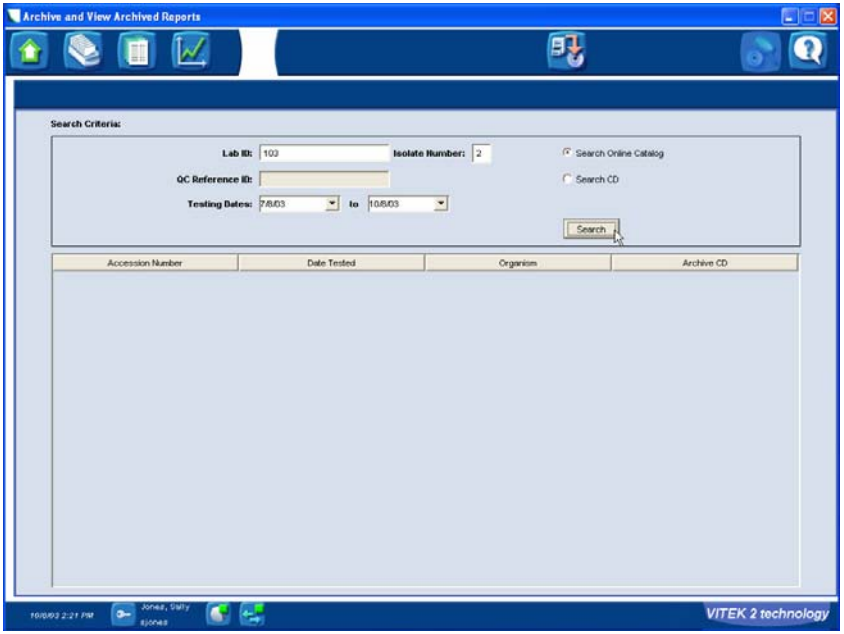

Figure 13-5: Archive and View Archived Reports

7) The list is sorted by Accession number followed by the date. The most recent date is displayed at the top. The following information is displayed:

- Laboratory Accession Number or QC Reference ID
- Date and time isolate was tested in the instrument
- Selected organism identification for the isolate
- Unique Identifier for the CD that contains the isolate report.

8) Select the isolate to view the Lab Report or Isolate Audit Trail.

9) Click the **Display Archived Report** icon.

10) Insert the appropriate CD.

Note: *If a CD is not already inserted, a message appears asking you to insert a CD.*

11) The View Archived Lab Reports or Isolate Audit Trail window appears.

12) In the report type, select **Lab Report** or **Isolate Audit Trail**.

13) If a Lab Report is selected, select the specific version of the lab report and click **Print**.

14) If the report is an Isolate Audit Trail, click **OK.** and the Isolate Audit Trail window appears**.** Click **Print** or **Export** to proceed.

Search Audit Trail

The audit trail search function allows you to track the system history, as well as the history of individual isolates. You can also search an Archive CD for archived data.

Searching Audit Trail by Isolates or by the Application (System)

There are multiple types of search criteria to help you refine your audit trail search.

To search the audit trail:

1) From Main view, select Utility View and then click **Search Audit Trail**.

Figure 13-6: Search Audit Trail

2) Select either Isolate or Application (system) as the Search Type.

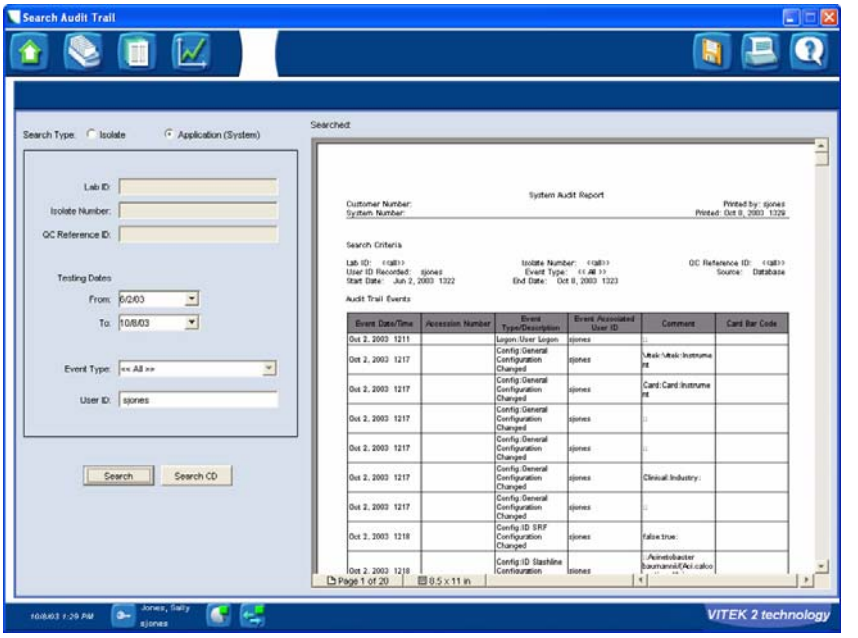

Figure 13-7: Search Audit Trail

3) From within the Search Audit Trail view, enter one or more of the following:

- Laboratory Identification Number
- Isolate Number
- QC Reference ID: Either Lab ID number or QC Reference ID is required. Entering the QC Reference ID is optional, if the Lab ID Number is entered.

Note: *You can use an asterisk as a wildcard in place of specific search criteria.*

- Enter a date range: Start Date and End Date
- User ID
- You can also filter your search by the following event types:

Table 13-4: Search Events

Isolate Events	Application Events
<<All>>	<<All>>
Approved	Backup

Table 13-4: Search Events

Isolate Events	Application Events
Archived	Cassette
Created	Configuration
Deleted	End of Day Processing
Ejected	Inactivity Timer Exceeded
Modified	Instrument Event
Report	Logon
Reviewed	Logon Failure
	Logout
	Restore
	SRF
	VITEK® 2 System Application Shutdown
	VITEK® 2 System Application Startup

4) After you have entered all of your search criteria, click **Search** to search the system or click **Search CD** to search the archived CD.

5) If you are performing a search from the Isolate Archive, be sure that an archive CD is inserted. An archived CD contains the following information:

- Isolate Lab Reports
- Isolate Audit
- Report Index
- Audit Index

6) The results appear in the table on the screen.

7) If you want to conduct a different search using different search criteria, change the criteria and click **Search** or **Search CD**.

8) Once you find the results you are looking for, click **Print** to get a printed copy of the Search Audit Results or click the **Save** icon to save the Audit Trail to a CD.

Note: *If the system software is associated with the event, the table displays System as the User ID.*

Saving Audit Trail to a CD

To save the Isolate and Application (system) Audit History in the form of a report to electronic media:

1) After you perform an Audit Trail Search, the audit history appears.

2) Click the **Save Audit Trail to a CD** icon.

Figure 13-8: Save Audit Trail to a CD Icon

3) Insert a blank CD.

Note: *If a CD is not already inserted, a message appears asking you to insert a blank CD.*

4) After you insert the CD, the system software validates the CD and copies the isolate audit report to a CD.

Exporting Results and Raw Data to Electronic Media

For support and troubleshooting ID and AST analysis, you can export raw data to a removable media.

To export Isolate and Raw Instrument Data in the form of a report to electronic media:

1) Insert a blank CD.

2) From within the View and Maintain Results view, click **Export Results**.

Figure 13-9: Export Results Icon

Note: *If a CD is not already inserted, a message appears asking you to insert a blank CD.*

3) After you insert the CD, the system software validates the CD and copies the isolate audit report to a CD.

Print Audit Trail Reports

An Audit Trail report allows you to print isolate and application audit information. To print the audit trail information, click the **Print** icon.

To search the audit database, see Search Audit Trail on page 13-13.

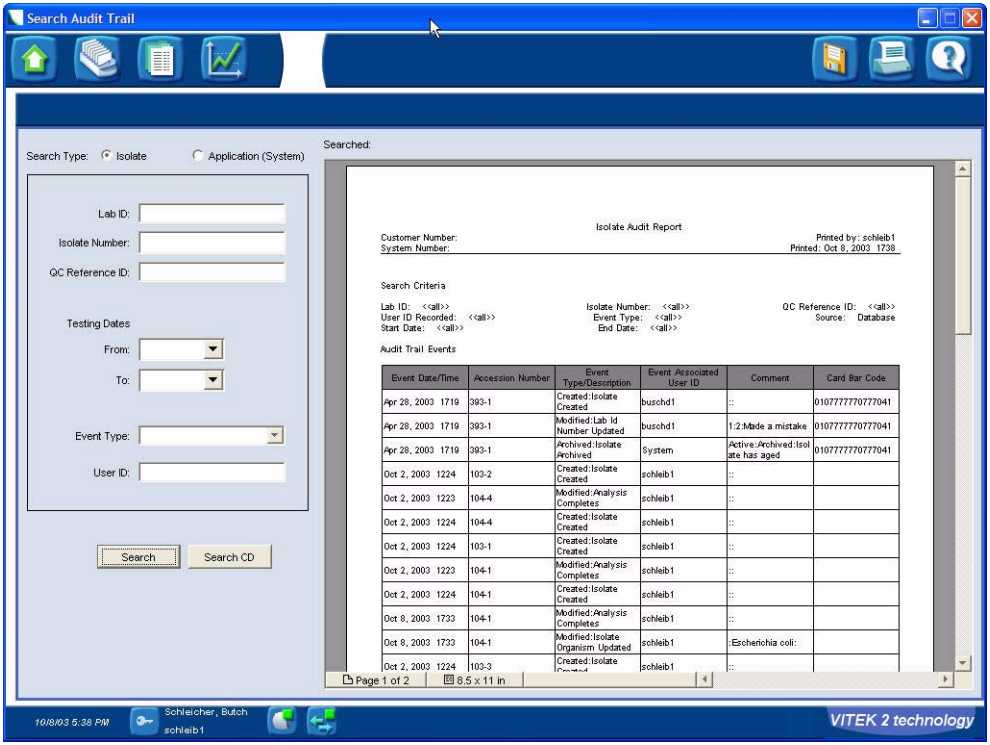
Search Audit Trail
Search Type: Isolate Application (System)
Lab ID:
Isolate Number:
QC Reference ID:
Testing Dates
From:
To:
Event Type:
User ID:
Search
Search CD
Searched:
Isolate Audit Report
Customer Number:
System Number:
Printed by: schleib1
Printed: Oct 8, 2003 1738
Search Criteria
Lab ID: <<all>>
User ID Recorded: <<all>>
Start Date: <<all>>
Isolate Number: <<all>>
Event Type: <<all>>
End Date: <<all>>
QC Reference ID: <<all>>
Source: Database
Audit Trail Events
Event Date/Time
Accession Number
Event Type/Description
Event Associated User ID
Comment
Card Bar Code
Apr 28, 2003 1719 393-1 Created:Isolate Created buschd1 :: 0107777770777041
Apr 28, 2003 1719 393-1 Modified:Lab Id Number Updated buschd1 1:2:Made a mistake 0107777770777041
Apr 28, 2003 1719 393-1 Archived:Isolate Archived System Active:Archived:Isolate has aged 0107777770777041
Oct 2, 2003 1224 103-2 Created:Isolate Created schleib1 ::
Oct 2, 2003 1223 104-4 Modified:Analysis Completes schleib1 ::
Oct 2, 2003 1224 104-4 Created:Isolate Created schleib1 ::
Oct 2, 2003 1224 103-1 Created:Isolate Created schleib1 ::
Oct 2, 2003 1223 104-1 Modified:Analysis Completes schleib1 ::
Oct 2, 2003 1224 104-1 Created:Isolate Created schleib1 ::
Oct 8, 2003 1733 104-1 Modified:Analysis Completes schleib1 ::
Oct 8, 2003 1733 104-1 Modified:Isolate Organism Updated schleib1 :Escherichia coli:
Oct 2, 2003 1224 103-3 Created:Isolate schleib1 ::
Page 1 of 2
8.5 x 11 in
10/8/03 5:38 PM
Schleicher, Butch
schleib1
VITEK 2 technology

Figure 13-10: Audit Trail Reports

DATA BACKUP AND DAILY MAINTENANCE 14

About This Chapter

This chapter describes end-of-day processing for the system software. All of the end-of-day processing is carried out by the system software. This chapter describes the automatic nightly maintenance and backup that occur without requiring any action by a Laboratory Technologist or Supervisor.

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Backup Isolate Data

Nightly backups of the database can be performed automatically and unattended.

Note: *It is recommended that you use read/write media (for example, CD-RW) for performing an unattended backup of isolate data.*

There are two methods for initiating backup; laboratory technologist initiated backup, or automatic backup. The database includes isolate information in the active workspace, information in the inactive workspace, and user custom setting.

System or automatic backup is enabled in the General Configuration view. For details, see Chapter 10 Enabling Automatic Daily Backup.

Note: *Be sure to change CDs daily. CD-RWs can be overwritten.*

Recommended Backup Strategy

It is very important to create a backup CD on a regular basis. The following instructions provide a recommended strategy to ensure all of your data is saved appropriately.

Daily

Use one CD-RW for each day of the week that the system is actively used. Substitute a new CD-RW at the end of each day to ensure that your data is properly saved on a regular basis.

Weekly

Once a week, replace one of the used CD-RWs with a new one. Permanently store the used CD-RW in a secure, climate controlled location as a weekly backup.

Note: *Make sure you replace the oldest CD-RWs first in order to keep the CD-RW media current.*

Long-Term Storage

For long-term storage, copy the CD-RW contents to a network drive or to a tape drive.

Automatic Backup

The system software can be set up to initiate nightly backup. When automatic backup is enabled or when a laboratory technologist initiates a backup, the system software will fail if any of the following items are found:

- CD contains isolate report archive
- CD contains export data
- CD is damaged (reliability for data storage)

If any of these conditions exist, the system software logs the backup failure and notes the reason for failure.

If none of these conditions are present, the system software performs the backup.

Note: *The automatic backup will overwrite any previous data backup on the inserted CD.*

CD Failure

If the CD fails during an unattended backup, the system software logs the backup failure and notes the reason for failure. This information can be considered an unacknowledged system software alarm and is displayed to the next user to log in. An automatic or unattended backup failure is logged in the alarm history.

If the backup was initiated by a laboratory technologist, the system software informs the laboratory technologist that backup failed and the message notes the reason for failure.

Laboratory Technologist Initiated Isolate Data Backup

To run and initiate Isolate Data Backup:

1) Insert a blank or read/write CD.

2) Select **Start** > **Programs** > **VITEK 2 Systems** > **VITEK 2 Systems Backup Restore.**

3) If the system software is running, you will be prompted to close the application before backup can begin.

4) You will then be prompted to log in to the application. For details on logging in, refer to chapter 2.

5) The system software will verify your *User ID* and *password*.

6) Select the **Backup** icon.

7) Once you log in, the system software notifies you that all system software services will be stopped to perform backup.

8) You will need to confirm stopping all services. If you do not confirm this process, no backup takes place.

9) If the CD has already been recorded, the system software will notify you that the CD contains information and you will be asked to confirm overwriting the CD.

- Choose **Yes** to continue backup.
- If you choose **No**, the system software returns to the Utilities window.

10) The system software checks the CD for use and continues with the backup process.

11) If no errors are found, isolate data backup is performed.

12) The system copies the entire VITEK® 2 Systems software database to the CD.

13) The workstation ejects the CD.

14) The workstation notifies the technologist that the backup is complete.

15) Select **OK**. The workstation automatically reboots.

End-of-Day Processing and Daily Maintenance

End-of-day processing occurs when the system is not in use. This usually occurs late at night in most labs. End-of-day processing is also the time when BCI transactions are at a minimum for upload and downloads. The default time that end of day processing begins is 3:00 AM. The system software application will not start if the end-of-day processing has begun.

If an error occurs during this nightly process, the system software applies all of the end-of-day processing that is not hindered by the error or simply does not get performed due to an error in the process.

End-of-Day Processing Begins

The system software automatically initiates end-of-day processing when the timer indicates it is time.

Complete Daily Workspace Maintenance

Nightly, the system software begins cleanup in the active workspace. The following section details what happens during cleanup. For details on

configuring end-of-day processing, see Chapter 10 Configure and Maintain Workstation.

Patient Information Cleanup

If patient demographics is enabled, the system software removes any aged (seven-day old) patients or specimens not linked to an isolate. A specimen will remain in the patient workspace for seven days after the specimen creation date. If a patient is not linked to any specimens, the system software deletes the patient from the patient workspace.

Isolate Information Cleanup

The system flags aged isolates for removal from the active workspace if they meet the following criteria:

- Not qualified
- Does not need to be reviewed
- Does not need to be approved
- Isolate is aged according to the number of days configured in General Configuration.

The system flags the isolates for removal from the active workspace, it also removes any other information related to the isolate.

QC Management Cleanup

QC Isolates in the active workspace are flagged as aged and to be removed from the active workspace based on the following criteria:

- Isolate is not qualified
- Isolate does not need to be reviewed
- Isolate does not need to be approved
- Isolate has aged based on the predefined number of days it is allowed to remain in the active workspace as configured in General Configurations. For details see Chapter 10 General Configuration.

If a QC Isolate is determined to be aged from the active workspace, then the system flags the QC Isolate and related QC components as inactive and removes them from the active workspace at end-of-day processing and sends them to the inactive workspace in QC cumulative. The inactive workspace/database is searched when you conduct a search from the Manage QC view.

Cassette Management Cleanup

All aged cassettes are removed from the active workspace. Cassettes that are loaded into an Instrument and which have no associated isolates in the active workspace are flagged as aged from the active workspace.

If a cassette is determined to be aged from the active workspace, then the cassette is deleted from the active workspace.

Instrument Status Management Cleanup

The system software removes aged messages from Instrument status active workspace. If the difference between the message creation date and current date is more than four months, then the message is deleted from the active workspace.

Alarm Management Cleanup

The system software maintains alarms from the active workspace by removing aged alarms. The system software applies the following criteria to delete alarms.

- If the difference between the alarm creation date and the current date is more than 31 days, then the alarm is deleted from the active workspace.
- If the number of retained alarms exceeds 1000, then the oldest alarms are deleted until the maximum number retained is 1000.

Deleted Isolates Cleanup

If 21 CFR 11 is enabled, the system software maintains deleted isolates in the active workspace until isolates are aged as configured in General Configurations. The deleted isolate is flagged as inactive and removed from the active workspace.

When 21 CFR 11 is disabled, deleted isolates do not remain in the active workspace.

Maintain Inactive Workspace

Cumulative Patient Isolate and Audit Management (Isolate Reports)

The system software maintains isolate reports in the inactive workspace by removing aged isolate reports. The system software applies the following criteria to remove isolates:

- If 21 CFR11, isolates must be flagged as **Archived**.
- If patient information is enabled in configuration, the oldest isolate reports are flagged to be removed from the inactive workspace if there are more than 20,000 isolate reports in the inactive workspace.

- If an isolate report is determined to be aged from the inactive workspace, the isolate and all related components are deleted.

Cumulative QC Isolate and Audit Management (Isolate Reports)

The system software maintains QC isolates in the inactive workspace by removing aged QC isolates. The system software applies the following criteria to remove QC isolates:

- If 21 CFR11 is enabled, isolates must be flagged as **Archived**.
- If there are more than 15,000 QC isolates in the active workspace, then the oldest QC isolates are flagged to be removed from the inactive workspace to keep the number of QC isolates near 15,000.
- If the QC isolate is determined to be aged from the inactive workspace, then the QC isolate is deleted.

Deleted Isolates in the Inactive Workspace

The system software maintains deleted isolate reports in the inactive workspace by removing aged isolate reports. The system software applies the following criteria to remove isolates:

- If 21 CFR11 is enabled, isolate must be flagged as **Archived**.
- If an isolate report is determined to be aged from the inactive workspace, then the isolate and all related components are deleted.

Application Audit Trail Management

Audit events are maintained by the application in the active and inactive workspace by removing aged audit events. The following criteria are used to determine when to remove aged application audit events:

- If 21 CFR11 is enabled, the application audit event must be flagged as **Archived**.
- If an audit event is determined to be aged from the active or inactive workspace, it is deleted.

Restore Isolate Data (Supervisor Only)

CAUTION: Contact bioMérieux support if you need to restore the isolate data. Restore should only be performed with help from authorized personnel from bioMérieux Customer Support.

If there is a problem and you need to restore the system data, you can do so from the backup CD containing the data. This should recover the data from a serious system error. The purpose of restoring the system data is to recover the system database. The isolate data includes raw data and any user-defined custom settings required to complete analysis.

Note: *The application services must not be running to perform a restore.*

To restore isolate data follow these steps:

1) Insert the isolate data backup CD.

2) To start the restore, **Start** > **Programs** > **VITEK 2 Systems** > **VITEK 2 Systems Backup Restore**.

Note: *A supervisor must log in to access utilities located outside the system software.*

3) Select the **Restore** icon.

4) When Restore starts up, the system software will check to see if the client is running. If the client is running, the system software notifies you that the restore failed and notes the reason for failure.

5) A message appears asking you to close the application before running a restore.

6) The system software will check for the following items:

- Isolate Data CD has been inserted. If the CD is not an isolate data CD, you can cancel the restore and insert the appropriate CD. The incompatible CD is ejected from the CD drive.
- Isolate data is compatible with the current system software installed on the system software. If the data is not compatible with the installed analysis software, you will need to restore the system software to the correct version. Then you will be able to restore the isolate data following the appropriate steps.

7) When the appropriate CD is available for restoring the system, you will be notified that the current user data will be deleted. You will be prompted to confirm deleting the current user data and proceed with restore isolate data.

8) When restore completes, the lab supervisor is notified that the data was successfully restored.

9) Click **OK**. The system reboots and the system software starts up automatically.

10) To begin using the software, you will need to log in again.

Restore Failure

If restoring isolate data fails, the workstation displays a message noting the reason for failure. Once you acknowledge the failure, contact bioMérieux for assistance.

VITEK® 2 Compact Blank Cassette Worksheet

General Information

Instrument Name: _____

Setup Date/Time: _____

Cassette Information

Cassette ID: _____

Bench Name: _____

Setup Tech Name: _____

Dilution Mode: _____

Slot	Card Type	Bar Code	Lab ID	Isolate Number	Organism	Offline Tests and Results	Organism Quantity
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

VITEK® 2 Blank Cassette Worksheet

General Information

Instrument Name: _____

Setup Date/Time: _____

Cassette Information

Cassette ID: _____

Bench Name: _____

Setup Tech Name: _____

Dilution Mode: _____

Slot	Card Type	Bar Code	Lab ID	Isolate Number	Organism	Offline Tests and Results	Organism Quantity
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

APPENDIX B: FORCING RULES B

Introduction

This Appendix contains the following configuration information for AES:

- CLSI™ Forcing Rules
- Global Forcing Rules
- CA-SFM Forcing Rules

CLSI Forcing Rules

IMPORTANT: ***CLSI™ Forcing rules will force the category call only, not the MIC.***

Rule 1

If the cefoxitin screen test (OXSF) is positive and oxacillin (OX1) is susceptible, the oxacillin MIC interpretation is forced resistant.

For speciated CNS other than *Staphylococcus epidermidis* and *Staphylococcus lugdunensis*, if the cefoxitin screen test (OXSF) is negative and the oxacillin (OX1) MIC is 0.5, 1 or 2, the oxacillin MIC interpretation is forced susceptible.

A note is included when a KeyID of "coagulase-negative *staphylococci*" is used (i.e., not speciated) indicating that inappropriate oxacillin breakpoints may be applied.

Note: *Final oxacillin interpretation after AES expertization is also dependent on the recognized ß-Lactam phenotype.*

If the test oxacillin (OX1) is resistant for the *Staphylococcus* species, then the results are automatically forced resistant for the following antibiotics:

Penicillins

Amoxicillin

Amoxicillin/Clavulanic Acid

Ampicillin/Sulbactam
Ampicillin
Azlocillin
Benzylpenicillin

Carbenicillin
Cloxacillin
Dicloxacillin
Methicillin
Mezlocillin
Nafcillin
Oxacillin
Piperacillin
Piperacillin/Tazobactam
Ticarcillin
Ticarcillin/Clavulanic Acid

Cephalosporins and Cephems

1st: Cefadroxil
Cefalotin
Cefalexin
Cefazolin
Cefradine

2nd: Cefaclor
Cefamandole
Cefmetazole
Cefonicid
Cefotetan
Cefoxitin (MIC test only, not the cefoxitin screen test)
Cefprozil
Ceftibuten
Cefuroxime-Sodium
Cefuroxime-Axetil

3rd: Cefetamet
Cefixime
Cefoperazone
Cefotaxime
Cefpodoxime
Ceftazidime
Ceftizoxime
Ceftriaxone

4th: Cefepime
Loracarbef

Carbapenems (Imipenem, Meropenem and Ertapenem)

Latamoxef (Moxalactam)

Rule 2

If any type of *Enterococcus* species is tested, then the result is automatically forced resistant for the following antibiotics:

Cephalosporins

1st: Cefadroxil
Cefalexin
Cefalotin
Cefazolin
Cefradine

2nd: Cefaclor
Cefamandole
Cefmetazole
Cefonicid
Cefotetan
Cefoxitin
Cefprozil
Ceftibuten
Cefuroxime-Sodium
Cefuroxime-Axetil

3rd: Cefatamet
Cefixime
Cefoperazone
Cefotaxime
Cefpodoxime
Ceftazidime
Ceftizoxime
Ceftriaxone

4th: Cefepime

Aminoglycosides

Amikacin
Gentamicin
Kanamycin
Netilmicin
Tobramycin

Clindamycin

Trimethoprim Sulfamethoxazole

Rule 3

If Beta-Lactamase (BLA) is positive when testing *Enterococcus* species, then the results are forced resistant for the following antibiotics.

Amoxicillin
Ampicillin
Azlocillin
Benzylpenicillin
Carbenicillin
Mezlocillin
Piperacillin
Ticarcillin

Note: *If the organism is an Enterococcus or a Staphylococcus species and any antibiotic on the card requires Beta-Lactamase (beta-lactamase is positive), then the card will not display SIR category calls until beta-lactamase is entered.*

Rule 4

If Beta-Lactamase (BLA) is positive when testing *Staphylococcus* species (Oxacillin [OX1]) sensitive or not available), the results are forced resistant for the following antibiotics:

Amoxicillin
Ampicillin
Azlocillin
Benzylpenicillin
Carbenicillin
Mezlocillin
Piperacillin
Ticarcillin

Note: *If the organism is an Enterococcus or a Staphylococcus species and any antibiotic on the card requires Beta-Lactamase (beta-lactamase is positive), then the card will not display SIR category calls until beta-lactamase is entered.*

Rule 5

If *Salmonella* spp. or *Shigella* spp. species are tested, then the results are forced resistant for the following antibiotics:

Cephalosporins

1st: Cefadroxil
Cefalexin

Cefalotin
Cefazolin
Cefradine

2nd: Cefaclor
Cefamandole
Cefonicid
Ceftibuten
Cefuroxime-Sodium
Cefuroxime-Axetil

Aminoglycosides

Amikacin
Gentamicin
Kanamycin
Netilmicin
Tobromycin

Rule 6

If *Candida krusei* is tested, then the results are forced resistant for the following antifungals:

Fluconazole

Global Forcing Rules

IMPORTANT: ***Global Forcing Rules will force the category call only, not the MIC.***

Rule 1

For speciated CNS other than *Staphylococcus epidermidis* and *Staphylococcus lugdunensis*, if the cefoxitin screen test (OXSF) is negative and the oxacillin (OX1) MIC is 0.5, 1 or 2, the oxacillin MIC interpretation is forced susceptible.

A note is included when a KeyID of "coagulase negative staphylococci" is used (i.e., not speciated), indicating that inappropriate oxacillin breakpoints may be applied.

Note: *Final oxacillin interpretation after AES expertization is also dependant on the recognized ß-lactam phenotype.*

Rule 2

If *Candida krusei* is tested, then the results are forced resistant for the following antifungals:

Fluconazole

CA-SFM Forcing Rules

IMPORTANT: ***CA-SFM Forcing Rules will force the category call only, not the MIC.***

Rule 1

If *Candida krusei* is tested, then the results are forced resistant for the following antifungals:

Fluconazole

APPENDIX C: AES ANTIBIOTIC DEDUCTION RULES C

Introduction

This Appendix contains the deduction rules for AES.

AES: Antibiotic Deduction Rules

SELECTION CRITERIA:
ANTIBIOTICS: All
SPECIES: All
INTERPRETATION GUIDELINES: All
ACTIVITY STATE: All

RULE: 1 INTERPRETATION GUIDELINES: PHENOTYPIC: Active

If

Staphylococcus

And

One of the following antibiotics has been tested
OXACILLIN MIC
OXACILLIN

And

The result is
R

Then

The result can be reported for
BETA-LACTAMS

RULE: 2 INTERPRETATION GUIDELINES: PHENOTYPIC: Active

If

Enterobacteriaceae

And

One of the following antibiotics has been tested
CEFALOTIN

Then

The result can be reported for
CEFAZOLIN
CEPHAPIRIN

RULE: 3 INTERPRETATION GUIDELINES: PHENOTYPIC: Active

If

Staphylococcus

And

One of the following antibiotics has been tested
KANAMYCIN

Then

The result can be reported for
AMIKACIN
ISEPAMICIN

RULE: 4 INTERPRETATION GUIDELINES:PHENOTYPIC: Active

If

Staphylococcus

And

One of the following antibiotics has been tested
GENTAMICIN

Then

The result can be reported for
NETILMICIN

RULE: 6 INTERPRETATION GUIDELINES: PHENOTYPIC: Active

If

Staphylococcus
Or *Streptococcaceae*

And

One of the following antibiotics has been tested
ERYTHROMYCIN

Then

The result can be reported for
AZITHROMYCIN
CLARITHROMYCIN
DIRITHROMYCIN

RULE: 7 INTERPRETATION GUIDELINES: PHENOTYPIC: ACTIVE

If

Enterobacteriaceae

And

One of the following antibiotics has been tested
NALIDIXIC ACID

Then

The result can be reported for
QUINOLONES 1

RULE: 8 INTERPRETATION GUIDELINES: PHENOTYPIC: Inactive

If

Acinetobacter baumannii

And

One of the following antibiotics has been tested
CIPROFLOXACIN
OFLOXACIN
PEFLOXACIN

And

The result is
S

Then

The result can be reported for
CIPROFLOXACIN
LEVOFLOXACIN
OFLOXACIN
PEFLOXACIN
SPARFLOXACIN

RULE: 9 INTERPRETATION GUIDELINES: PHENOTYPIC: Active

If

Staphylococcus

And

One of the following antibiotics has been tested
CIPROFLOXACIN
LEVOFLOXACIN
OFLOXACIN
PEFLOXACIN

Then

The result can be reported for
CIPROFLOXACIN
LEVOFLOXACIN
OFLOXACIN
PEFLOXACIN

RULE: 10 INTERPRETATION GUIDELINES: PHENOTYPIC: Active

If

Enterobacteriaceae

And

One of the following antibiotics has been tested
NORFLOXACIN

And

The result is
S

Then

The result can be reported for
CIPROFLOXACIN
ENOXACIN
GATIFLOXACIN
LEVOFLOXACIN
LOMEFLOXACIN
MOXIFLOXACIN
OFLOXACIN
PEFLOXACIN

RULE: 221 INTERPRETATION GUIDELINES: PHENOTYPIC: Active

If

Enterobacteriaceae
Or *Enterococcus*
Or *Staphylococcus*
Or *Streptococcus*
Or *Streptococcus pneumoniae*

And

One of the following antibiotics has been tested
TETRACYCLINE

Then

The result can be reported for
DOXYCYCLINE

RULE: 241 INTERPRETATION GUIDELINES: PHENOTYPIC: Active

If

Enterococcus faecalis

And

One of the following antibiotics has been tested
AMPICILLIN

Then

The result can be reported for
AMOXICILLIN
BENZYLPENICILLIN

IMIPENEM
PIPERACILLIN

RULE: 21 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Enterobacteriaceae

And

One of the following antibiotics has been tested
MEZLOCILLIN
PIPERACILLIN

Then

The result can be reported for
MEZLOCILLIN
PIPERACILLIN

RULE: 22 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Enterobacteriaceae

And

One of the following antibiotics has been tested
AMOXICILLIN+CLAVULANIC ACID
AMPICILLIN+SULBACTAM

Then

The result can be reported for
AMOXICILLIN+CLAVULANIC ACID
AMPICILLIN+SULBACTAM

RULE: 23 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Enterobacteriaceae

And

One of the following antibiotics has been tested
CEFAMANDOLE
CEFONICID
CEFUROXIME

Then

The result can be reported for
CEFAMANDOLE
CEFONICID
CEFUROXIME

RULE: 24 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Enterobacteriaceae

And

One of the following antibiotics has been tested
CEFOTAXIME
CEFTIZOXIME
CEFTRIAXONE

Then

The result can be reported for
CEFOTAXIME
CEFTIZOXIME
CEFTRIAXONE

RULE: 25 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Enterobacteriaceae

And

One of the following antibiotics has been tested
LOMEFLOXACIN
NORFLOXACIN
OFLOXACIN

Then

The result can be reported for
LOMEFLOXACIN
NORFLOXACIN
OFLOXACIN

RULE: 26 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Enterobacteriaceae

And

One of the following antibiotics has been tested
AMPICILLIN

Then

The result can be reported for
AMOXICILLIN

RULE: 27 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Enterobacteriaceae

And

One of the following antibiotics has been tested
CEFALOTIN

Then

The result can be reported for
CEFACLOR
CEFRADINE
CEFADROXIL
CEFALEXIN
CEPHAPIRIN

RULE: 28 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Acinetobacter baumannii
Or *Pseudomonas* group

And

One of the following antibiotics has been tested
CEFOTAXIME
CEFTRIAXONE

Then

The result can be reported for
CEFOTAXIME
CEFTRIAXONE

RULE: 30 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Acinetobacter baumannii
Or *Pseudomonas* group

And

One of the following antibiotics has been tested
LOMEFLOXACIN
NORFLOXACIN
OFLOXACIN

Then

The result can be reported for
LOMEFLOXACIN
NORFLOXACIN
OFLOXACIN

RULE: 31 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Staphylococcus

And

One of the following antibiotics has been tested
AZITHROMYCIN
CLARITHROMYCIN
ERYTHROMYCIN

Then

The result can be reported for
AZITHROMYCIN
CLARITHROMYCIN
ERYTHROMYCIN

RULE: 32 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Staphylococcus

And

One of the following antibiotics has been tested
CIPROFLOXACIN
LEVOFLOXACIN
OFLOXACIN

Then

The result can be reported for
CIPROFLOXACIN
LEVOFLOXACIN
OFLOXACIN

RULE: 33 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Staphylococcus

And

One of the following antibiotics has been tested
LOMEFLOXACIN
NORFLOXACIN

Then

The result can be reported for
LOMEFLOXACIN
NORFLOXACIN

RULE: 34 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Staphylococcus

And

One of the following antibiotics has been tested
BENZYLPENICILLIN

And

The result is
S

Then

The result can be reported for
AMINO-PENICILLINS
AMINO-PENICILLINS + BETA-LACTAM INHIBITOR
CEFACLOR
CEFADROXIL
CEFALEXIN
CEFDINIR
CEFDITOREN
CEFPROZIL
CEPHAPIRIN
CEFALOTIN
CEFAMANDOLE
CEFAZOLIN
CEFEPIME
CEFMETAZOLE
CEFONICID
CEFOPERAZONE
CEFOTAXIME
CEFPODOXIME
CEFRADINE
CEFTAZIDIME
CEFTIZOXIME
CEFTRIAXONE
CEFUROXIME
CEFUROXIME AXETIL
CEPHAMYCINS
CLOXACILLIN
DICLOXACILLIN
LATAMOXEF
LORACARBEF
METHICILLIN
NAFCILLIN
PENEMS
PIPERACILLIN+TAZOBACTAM

TICARCILLIN+CLAVULANIC ACID

RULE: 35 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Staphylococcus

And

One of the following antibiotics has been tested
OXACILLIN MIC
OXACILLIN

And

The result is R

Then

The result can be reported for
BETA-LACTAMS

RULE: 38 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Streptococcus pneumoniae

And

One of the following antibiotics has been tested
AMOXICILLIN
AMOXICILLIN+CLAVULANIC ACID

Then

The result can be reported for
AMOXICILLIN
AMOXICILLIN+CLAVULANIC ACID

RULE: 39 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Streptococcus pneumoniae

And

One of the following antibiotics has been tested
CEFOTAXIME
CEFTRIAXONE

Then

The result can be reported for
CEFOTAXIME
CEFTRIAXONE

RULE: 40 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Streptococcus pneumoniae

And

One of the following antibiotics has been tested
GATIFLOXACIN
LEVOFLOXACIN
MOXIFLOXACIN
SPARFLOXACIN

Then

The result can be reported for
GATIFLOXACIN
LEVOFLOXACIN
MOXIFLOXACIN
SPARFLOXACIN

RULE: 41 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Streptococcus pneumoniae

And

One of the following antibiotics has been tested
BENZYLPENICILLIN

And

The result is
S

Then

The result can be reported for
AMOXICILLIN
AMOXICILLIN+CLAVULANIC ACID
AMPICILLIN
AMPICILLIN+SULBACTAM
CEFACLOR
CEFDINIR
CEFEPIME
CEFETAMET
CEFIXIME
CEFOTAXIME
CEFPODOXIME
CEFPROZIL
CEFTIBUTEN
CEFTIZOXIME
CEFTRIAXONE
CEFUROXIME

ERTAPENEM
IMIPENEM
LORACARBEF
MEROPENEM

RULE: 42 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Streptococcus pneumoniae

And

One of the following antibiotics has been tested
ERYTHROMYCIN

Then

The result can be reported for
AZITHROMYCIN
CLARITHROMYCIN
DIRITHROMYCIN

RULE: 43 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Streptococcus pneumoniae

And

One of the following antibiotics has been tested
OFLOXACIN

And

The result is
S

Then

The result can be reported for
LEVOFLOXACIN

RULE: 44 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Streptococcus agalactiae

And

One of the following antibiotics has been tested
AMPICILLIN
BENZYLPENICILLIN

Then

The result can be reported for
AMPICILLIN
BENZYLPENICILLIN

RULE: 45 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Streptococcus agalactiae

And

One of the following antibiotics has been tested
CEFEPIME
CEFOTAXIME
CEFTRIAXONE

Then

The result can be reported for
CEFEPIME
CEFOTAXIME
CEFTRIAXONE

RULE: 46 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Streptococcus agalactiae

And

One of the following antibiotics has been tested
BENZYLPENICILLIN

And

The result is
S

Then

The result can be reported for
AMOXICILLIN
AMOXICILLIN+CLAVULANIC ACID
AMPICILLIN
AMPICILLIN+SULBACTAM
CEFACLOR
CEFALOTIN
CEFAZOLIN
CEFDINIR
CEFEPIME
CEFOTAXIME
CEFPODOXIME
CEFPROZIL
CEFRADINE
CEFTIZOXIME
CEFTRIAXONE
CEFUROXIME
CEPHAPIRIN
ERTAPENEM

IMIPENEM
LORACARBEF
MEROPENEM

RULE: 47 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Streptococcus agalactiae

And

One of the following antibiotics has been tested
ERYTHROMYCIN

Then

The result can be reported for
AZITHROMYCIN
CLARITHROMYCIN
DIRITHROMYCIN

RULE: 63 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Enterobacteriaceae

And

One of the following antibiotics has been tested
CIPROFLOXACIN
LEVOFLOXACIN

Then

The result can be reported for
CIPROFLOXACIN
LEVOFLOXACIN

RULE: 64 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Acinetobacter baumannii
Or *Pseudomonas* group

And

One of the following antibiotics has been tested
MEZLOCILLIN
TICARCILLIN

Then

The result can be reported for
MEZLOCILLIN
TICARCILLIN

RULE: 101 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Staphylococcus

And

One of the following antibiotics has been tested
OXACILLIN MIC
OXACILLIN

And

The result is
S

Then

The result can be reported for
AMOXICILLIN+CLAVULANIC ACID
AMPICILLIN+SULBACTAM
CEFACLOR
CEFADROXIL
CEFALEXIN
CEFALOTIN
CEFAMANDOLE
CEFAZOLIN
CEFDINIR
CEFDITOREN
CEFEPIME
CEFMETAZOLE
CEFONICID
CEFOPERAZONE
CEFOTAXIME
CEFOTETAN
CEFOXITIN
CEFPODOXIME
CEFRADINE
CEFROZIL
CEFTAZIDIME
CEFTIZOXIME
CEFTRIAXONE
CEFUROXIME
CEFUROXIME AXETIL
CEPHAPIRIN
CLOXACILLIN
DICLOXACILLIN
ERTAPENEM
IMIPENEM
LATAMOXEF
LORACARBEF

MEROPENEM
METHICILLIN
NAFCILLIN
PIPERACILLIN+TAZOBACTAM
TICARCILLIN+CLAVULANIC ACID

RULE: 121 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Enterobacteriaceae

And

One of the following antibiotics has been tested
IMIPENEM
MEROPENEM

Then

The result can be reported for
IMIPENEM
MEROPENEM

RULE: 122 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Staphylococcus

And

One of the following antibiotics has been tested
BENZYLPENICILLIN

Then

The result can be reported for
AMOXICILLIN
AMPICILLIN
AZLOCILLIN
CARBENICILLIN
MEZLOCILLIN
PIPERACILLIN
TICARCILLIN

RULE: 281 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Acinetobacter baumannii
Or *Enterobacteriaceae*
Or *Enterococcus*
Or *Pseudomonas* group
Or *Staphylococcus*

And

One of the following antibiotics has been tested
TETRACYCLINE

And

The result is S

Then

The result can be reported for
DOXYCYCLINE
MINOCYCLINE

RULE: 282 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Enterococcus

And

One of the following antibiotics has been tested
BENZYLPENICILLIN

Then

The result can be reported for
AMOXICILLIN
AMPICILLIN
PIPERACILLIN

RULE: 283 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Enterococcus

And

One of the following antibiotics has been tested
AMPICILLIN

Then

The result can be reported for
AMOXICILLIN
PIPERACILLIN

RULE: 284 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Enterococcus

And

One of the following antibiotics has been tested
AMPICILLIN
BENZYLPENICILLIN

And

The result is S

Then

The result can be reported for
AMOXICILLIN+CLAVULANIC ACID
AMPICILLIN+SULBACTAM
PIPERACILLIN+TAZOBACTAM

RULE: 585 INTERPRETATION GUIDELINES: NATURAL RESISTANCE: Active CLSI™ M100-S15 (2005): Active

If

Staphylococcus

And

One of the following antibiotics has been tested
GATIFLOXACIN
MOXIFLOXACIN

Then

The result can be reported for
GATIFLOXACIN
MOXIFLOXACIN

RULE: 584 INTERPRETATION GUIDELINES: PHENOTYPIC: Active

If

Staphylococcus
Or *Streptococcus pneumoniae*

And

One of the following antibiotics has been tested
LINCOMYCIN

Then

The result can be reported for
CLINDAMYCIN

Glossary

Accession ID number — The Accession ID number is a unique alphanumeric number that identifies a card to the system. The Accession ID number may be up to 20 digits in length. The number includes a dash and single-digit isolate number.The length of the Accession ID number determines the number of digits you will have available for autolinking.

Advanced Expert System™ — Software that takes instrument *MICs*, *Category Calls*, and an *Organism* ID and compares them to typical *Phenotypes* for that Organism. AES reports findings in the form of summary statements and propositions.

AES — Advanced Expert System.

Antibiotic — A drug that kills microorganisms or suppresses their growth.

Antimicrobial — Alternate for Antibiotic.

Antimicrobial Susceptibility Testing — Testing the susceptibility of certain bacteria to known antibiotic concentrations. The test measures the ability of an organism to grow within various concentration levels.

Application — Software that runs on a computer and performs a designated procedure or process.

Archive (data) — When 21 CFR 11 is enabled, archive is the process of saving a copy of isolate reports including all associated audit information from the database to a CD.

AST — Antimicrobial Susceptibility Test.

AST card — Antimicrobial Susceptibility Test card. A test card that measures how an organism is affected by antimicrobial agents.

AST Card Definitions — The list of bar codes that when entered into *Maintain AST Card Definitions* introduces a new test kit to the software.

Backup — The process of saving the entire database including VITEK® 2 Systems software configuration to a CD.

Basis — Refers to the official interpretation standard a user-defined custom interpretation standard is based on.

Bar Code
1) A CODE37 interface identifier label affixed to each *VITEK® 2* test card. The bar code contains the card's test type, lot number, and expiration date. The bar code is entered into the system when the *Bar Code Reader* scans the test card's bar code label. In VITEK® 2, bar codes can also be entered by the Smart Carrier Station.
2) An alphanumeric identifier for the configuration of the susceptibility panel located on the package insert. The bar code is entered into the *Maintain AST Card Definitions* prior to running the susceptibility card.

Bar Code Reader
A station in the VITEK® 2 instruments that reads the Bar Code label on each test card. As cards are read, the associated data (along with its corresponding bar code) is transferred to the workstation.

Bench Name
An alphanumeric name that tags a bench where a given cassette was set up. The VITEK® 2 Systems software supports an alphanumeric value of up to any 20 valid characters.

Biochemical
A substrate on an identification card; also known as a biochemical test or biochemical formulation.

Biochemical Reaction
The result from an Identification Card *Well* as determined by analysis parameters. Also known as Biochemical Result.

Biological Validation
The process of determining whether observed Susceptibility results for an organism are consistent with the antibiotic's susceptibility patterns (phenotype) in the AES knowledgebase.

Bionumber
Number in octal code that represents the reaction-pattern profile produced by analysis. Place value of 1-2-4 is assigned for positive reactions in each group of three tests, and the value in each group is summed to give an integer between zero and seven. The computer assigns a bionumber to each set of identification results.

Call
Reactions

Card
See *Test Card*.

Card Lot Number
A nine-digit number encoded with Card Type, Expiration Date, manufacturing line, and dash number.

Card Name
Official test card name that is given to a product.

Card Type	Abbreviated card name, consisting of multiple character product name. The card type may have an optional dash followed by a 4-character identifier. For example, GN or AST-GN01. The unique code which identifies an individual cassette to the VITEK® 2 Systems software. It is a combination of the cassette ID and slot number, plus a time and date stamp from when the cassette was presented to the instrument.
Cassette Definition	The setup information that prepares a cassette for insertion into an instrument.
Category Call	Categorical values resulting from a call such as S (Susceptibility), I (Intermediate), or R (Resistant) applied to an MIC result.
Confidence Level	A qualitative level for the identification that corresponds to the percent probability value assigned to a given biopattern analysis.
Contraindicating Tests	Tests identified by the Identification Data Analysis Algorithm to be suspect for a particular card result; e.g. a negative result for one or more biochemical with an expected positive value for that given species.
Data Management System	Generic name for any third-party data system.
Deduced Antibiotic	Antibiotic results that are not tested on the AST card, but the category interpretation is reported based on tested antibiotics and/or recognized phenotypes.
Demographics	Information about the Patient, Sample or Isolate that is being tested. Examples include Patient ID, Patient Name, Specimen source, and Accession ID.
Electronic Signature	A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's hand written signature.
Expected Therapeutic Response	List of category calls expected for a given antibiotic and given phenotype. The list is dependent on interpretation guidelines. It can be different from the list of category calls obtained by a comparison of the Interpretation breakpoints to the MIC distribution for the same phenotype and the same antibiotic. If there is a potential risk that the resistance conferred by the corresponding resistance mechanism is poorly expressed *in vitro*; this situation can lead to a therapeutic correction proposition.

Expert	See *Advanced Expert System™*.
Expiration Date	The last date on which a *Test Card* can be used; each lot number receives a value supplied at time of manufacture.
Filter	A type of search criteria used to limit information displayed in a view.
Final	An indication that a test or exam's result is complete.
Hour of call	The hour a card result becomes final.
ID test card	A test card that identifies microorganisms.
Instrument	A VITEK® 2 instrument used to process tests by the insertion of Cassettes/Test Cards.
Instrument Parameters	Operating parameters for the VITEK® 2 instruments such as incubation temperature, wavelength, and optical spectra used.
Instrument Raw Data	Raw transmittance units (RTU) expressed as a number between 0 and 4095.
Interpretation	A category call such as S (susceptible), I (intermediate), or R (resistant) that is applied to an MIC result.
Interpretation Guideline	A parameter allowing users to select sets of expected therapeutic interpretation and antibiotic deduction rules (e.g., CLSI, CA-SFM, and Natural Resistance).
Interpretation set or standard	A set of antibiotic Susceptibility Category breakpoints, recommended by a recognized consensus committee.
Isolate	A bacterial microorganism recovered from a clinical or industrial specimen that is potentially *Pathogenic*. Isolates recovered from the same culture are distinguished from each other by an *Isolate Number* assigned by the Lab Tech; e.g., 1=E. coli, an Isolate recovered from a urine specimen.
Isolate Group	A collection of *Test Cards* used to test an *Isolate*. The Isolate Group is created by the Microbiologist during setup and groups cards based on the Laboratory Identification Number, Isolate Number, and Cassette.
Isolate Number	The number following the dash on an Accession ID that refers to a specific isolate. Isolate numbers can include the digits 1 to 99.
Knowledge Base	The database of raw data, reference identifications, and algorithm parameters used for a particular product (e.g., GP).

LIS	Laboratory Information System.
Lab Information System	A computer system used to collect and report laboratory data.
Laboratory Identification Number	A number used to identify a laboratory culture. It can be assigned manually or by the Lab Information System. Values of up to 20 alphanumeric characters are allowed.
Load Time	Indicated when the cassette was loaded into the instrument: the month, date, and the time expressed in hours minutes, and seconds.
Lot number	Each lot of test cards has a unique identification, called the lot number, which is assigned by the manufacturer. If you receive two or more shipments from the same lot, the VITEK® 2 Systems software assigns a consecutive dash number to the lot number (for example, -1, -2, etc.).
Low Discrimination	An analysis message which indicates biochemical results for an organism closely resemble the species pattern of two or more closely related organisms.
Minimum Inhibitory Concentration	Minimum inhibitory concentration measured in micrograms per milliliter (µg/mL). Commonly referred to as MIC.
Natural Resistance	The organism is inherently resistant to an antibiotic in its natural state (wild type), without any acquired or induced resistance mechanisms.
Negative Reaction	The condition attributed to a *Well* when its *Percent Growth* reaction does not meet a predetermined threshold level. A weak negative reaction is slightly below the predetermined threshold level.
Organism ID	Identification of a microorganism provided by the identification card.
Organism Quantity	A subjective value describing the amount of organism growing on an Isolation Medium. Current practice includes phrase and number definitions (e.g., growth of five colonies would be described as 'rare' or '5'). In the VITEK® 2 Systems software, the value is a free field attached to the individual cassette.
Patient	Demographic information concerns the source of a specimen in clinical system applications.
Pathogenic	Disease-producing agents or microorganisms; Pathogenic is the adjectival from of Pathogen.

Phenotype The wild type pattern or the expression of one resistance mechanism of one species for one antibiotic family (e.g. E.Coli/ penicillinase, beta/lactam antibiotics).

Positive Reaction The condition attributed to a *Well* when its *Percent Growth* reaction meets or exceeds a predetermined threshold level. A weak positive reaction is slightly above the predetermined threshold level.

Quality control A special VITEK® 2 Systems software program that validates testing analysis and cards against a set of control organisms.

Raw data A set of instrument readings on a card that can be useful when troubleshooting the system.

React File A table of positive reaction percent probabilities for each organism and for each biochemical test.

Reference ID A special identification number which differentiates a quality control organism from a clinical isolate.

Resistance Mechanism A genetically-determined property allowing a bacterial strain to be resistant to certain antibiotics within a family. In *AES*, the association of several resistance mechanisms within the same antibiotic family is considered to be another resistance mechanism.

Setup Technologist A staff member entrusted to setup cassettes, view, and maintain data in the VITEK® 2 Systems software. Access rights (established through their identity in Windows) determine the number and type of screens available to the technologist.

Shipment A set of Test Cards and Disposables received from bioMérieux, Inc.

Slot Number A number that designates from which slot in the cassette the card originated from.

Specimen The material received in a laboratory for testing.

Standard Same as Interpretation set. A set of category calls that has been compiled by a recognized consensus committee and applied in a particular country.

Susceptibility The *in vitro* measurement of an organism's ability to replicate when it is exposed to specific antibiotic concentrations.

System user	The user group ID for the user currently logged on to the computer
Tab	The portion of a folder that contains the folder's label or function title.
Test Card	A plastic, disposable card consisting of a set number of wells that contains either biochemical substrates (for identification purposes) or antimicrobial concentrations (for susceptibility testing of microbes). Commonly referred to as 'Card.'
Test type	A multiple character product name indicating the kind of test card. The test type may have an optional dash followed by a four-character identifier.
Tested antibiotic	The antimicrobial agent on a susceptibility card.
Therapeutic Interpretation Changes	A modification message where AES recommends changes to category interpretations based on CLSI™, CA-SFM, Natural Resistance or another committee's recommendation.
Therapeutic Interpretation	An interpretation of the susceptibility results after biological validation. AES can propose interpretation changes and deduce results for untested antibiotics.
Toolbar	The area at the top of a software window that contains program icons. Different icons in the toolbar represent certain functions, such as printing, viewing, and deleting.
UPS	Uninterrruptible Power Supply
User Interface	The visual connection made between a software Application and the user. Current Applications tend to use graphic representations for some interface options (notably mouse selection) and are referred to as *Graphical User Interface* (GUI).
View	Any of a series of separate program windows. Most views contain software options or settings that control a set of related tasks.

Well A space filled with a biochemical on a test card. Well locations determine the specific Antibiotic or biochemical on a given card type.

Well Number The number of the well on a *Test Card*.

Workstation A central diagnostic station connected to the instrument communication port via a RS232 cable. Under normal conditions, the instrument will send system status, test card data, and operational data to the workstation. It allows instrument data entry and calculates test results. The workstation can also be used as a means to interface the VITEK® 2 instruments with other computer systems. The instrument is capable of buffering data for up to 18 hours should the computer fail.

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CE

VITEK® 2

Systems Product Information

bioMérieux, Inc.
Box 15969
Durham, North Carolina 27704-0969 / USA
Tel. (1) 800-682-2666

EC REP

bioMérieux® sa
au capital de 11 879 045 €
673 620 399 RCS LYON
69280 Marcy l'Etoile / France
tél. 33 (0)4 78 87 20 00 / fax 33 (0)4 78 87 20 90
http://www.biomerieux.com

Argentina
bioMérieux Argentina s.a.
Av. Congreso 1745
(C1428BUE) Capital Federal
Buenos Aires
tel. (54) 11 5555-6800
fax (54) 11 5555-6888

Australia
bioMérieux Australia P/L
Unit 25, Parkview Business Center
1 Maitland Place
Baulkham Hills NSW 2153
tel. (61) 2 8852 4700
fax (61) 2 8852 4777

Austria
bioMérieux Austria GmbH
Eduard-Kittenberger-Gasse 97
Top 3
A-1230 Wien
tel. (43) 186 50 650
fax (43) 186 50 661

Belgium
bioMérieux Benelux s.a./n.v.
Media Square
18–19 Place des Carabiniers
Bruxelles 1030
tel. (32) 2 743 01 70
fax (32) 2 733 55 97

Brazil
bioMérieux Brasil SA
Estrada Do Mapuá
491 Taquara - Jacarepaguá
CEP 22710 261 Rio de Janeiro RJ
tel. (55) 21 2444 1400
fax (55) 21 2455 6099

Canada
bioMérieux Canada, Inc.
7815, Henri-Bourassa West
Saint Laurent, QC
H4S 1P7
tel. (1) 514 336 7321
fax (1) 514 807 0015

Chile
bioMérieux Chile S.A.
Seminario 131
Providencia
Santiago
tel. (56) 2634 20 92
fax (56) 2634 20 93

China
bioMérieux China Limited
17/Floor, Yen Sheng Centre,
64 Hoi Yuen Road,
Kwun Tong
Kowloon - Hong Kong
tel. (852) 2356.7033
fax (852) 2330.2085

Colombia
bioMérieux Colombia Ltda
Avenida 15 No. 100-43
Piso 2
Bogotá D.C.
tel. (57) 1 520 0080
fax (57) 1 520 0088/1 520 0831

Denmark
bioMérieux Danmark Aps
Smedeholm 13C
2730 Herlev
tel. (45) 70 10 84 00
fax (45) 70 10 84 01

Finland
bioMérieux Suomi Oy
Rajatorpantie 41 C
01640 Vantaa
tel. (358) 9 8545 6000
fax (358) 9 8545 6045

France
bioMérieux SA
69280 Marcy l'Etoile
tel. (33) 0(4) 78 87 20 00
fax (33) 0(4) 78 87 20 90
http://www.biomerieux.com

Germany
bioMérieux Deutschland GmbH
Weberstrasse 8
D 72622 Nürtingen
tel. (49) 7022 30070
fax (49) 7022 36110

Greece
bioMérieux Hellas S.A.
Papanikoli 70
15232 Halandri
Athens
tel. (30) 210 81 72 400
fax (30) 210 68 00 880

Hungary
Representation Office
bioMérieux B.V.
Reitter Ferenc u. 39-49
1135 Budapest
tel. (36) 1 412 3880
fax (36) 1 412 3890

India
bioMérieux India Pvt. Ltd
D-45, Defense Colony
New Delhi 110 024
tel. (91) 11 2 464 88 40
fax (91) 11 2 464 88 30

Indonesia
bioMérieux Asean
Enseval Building
Kawasan Industri Pulo Gadung -
Jl. Pulo
Lentut No. 10
Jakarta Timur 13920
tel. (62) 21 461 51 11
fax (62) 21 460 41 07

Italy
bioMérieux Italia S.p.A.
Via Fiume Bianco, 56
00144 Roma
tel. (39) 06 52308.1
fax (39) 06 52308.240

Ivory Coast
bioMérieux Afrique Occidentale
08 BP 2634
Abidjan 08
tel. (225) 22 40 93 93/22 40 41 40
fax (225) 22 40 93 94

Japan
bioMérieux Japon, Ltd.
Seizan Bldg.,
12-28 Kita-Aoyama 2-chome
Minato-ku, Tokyo 107-0061
tel. (81) 3 5411 86 91
fax (81) 3 5411 86 90

Korea
bioMérieux Korea Co., Ltd.
7th Floor YooSung Building
830-67, Yoksam-dong,
Kangnam ku
Séoul
tel. (82) 2.547.6262
fax (82) 2.547.6263

Mexico
bioMérieux México SA de CV
Chihuahua 88, col. Progreso
México 01080, D.F.
tel. (52) 55 5481 9550
fax (52) 55 5616 2245

Netherlands (The)
bioMérieux Benelux BV
Boseind 15
P.O. Box 23
5280 AA Boxtel
tel. (31) 411 65 48 88
fax (31) 411 65 48 73

New Zealand
bioMérieux New Zealand Ltd.
22/10 Airbourne Road
North Harbour Auckland
tel. (64) 9 415 0601
fax (64) 9 415 0603

Norway
bioMérieux Norge AS
Økernveien 145
N-0513, Oslo
tel. (47) 23 37 55 50
fax (47) 23 37 55 51

Philippines (The)
Representation Office
bioMérieux Phillipines Rep. Office
11th Floor, Pearlbank Centre
146 Valero Street, Salcedo Village
1227 Makati City
tel. (632) 817 7741
fax (632) 812 0896

Poland
bioMérieux Polska Sp. Z.o.o.
ul. Zeromskiego 17
01-882 Warszawa
tel. (48) 22 569 85 00
fax (48) 22 569 85 54

Portugal
bioMérieux Portugal, Lda.
Rua Alto do Montijo, Lotes 1 e 2
Portela de Carnaxide
2794-070 Carnaxide
tel. (351) 21 424 59 80
fax (351) 21 418 32 67

Russia
o.o.o. bioMérieux
Petrovsko-Razoumovskii proyezd, 29
127287 Moscow
tel. (7) 095 212 10 26
(7) 095 424 79 38
fax (7) 095 214 95 41

Spain
bioMérieux España S.A.
Manual Tovar, 45–47
28034 Madrid
tel. (34) 91.358 11 42
fax (34) 91.358 06 29

Sweden
bioMérieux Sverige AB
Hantverksvägen 15
436 33 Askim
tel. (46) 31 68 84 90
fax (46) 31 68 48 48

Switzerland
bioMérieux Suisse s.a.
51, avenue Blanc
Case postale 2150
1211 Genève 2
tel. (41) 22.906 57 60
fax (41) 22.906 57 42

Taiwan
Representation Office
bioMérieux China Limited - Taiwan Branch
RM 608, No. 6-3 Ching Cheng Street
Taipei 105
tel. (886) 2 2545 2250
fax (886) 2 2545 0959

Thailand
bioMérieux Thailand Ltd
Regent House Bldg, 16th Floor
183 Rajdamri Road, Lumpini,
Pathumwan
Bangkok 10330
tel. (66) 2 651 98 00
fax (66) 2 651 98 01

Turkey
bioMérieux Diagnostik A.S.
Değirmen Sok. Nida Plaza Kat:6
34742 Kozyatağı/Istanbul
tel. (90) 216 444 00 83
fax (90) 216 373 16 63

United Kingdom
bioMérieux UK Ltd
Grafton Way, Basingstoke
Hampshire RG22 6HY
tel. (44) 1256.461881
fax (44) 1256.816863

USA
bioMérieux, Inc.
100 Rodolphe Street
Durham NC 27712
tel. (1) 919 620 2000
fax (1) 919 620 2211

Vietnam
Representation Office
bioMérieux Vietnam Rep. Office
17 Nguyen Van Mai, Ward 8
District 3
Ho Chi Minh City
tel. (84) 88 299 599
fax (84) 88 207 898

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STANDARD SYMBOLS

Table Of Symbols

Symbols that may appear in the instructions for use or on the instrument, package inserts, or packaging include:

CE-Marking of Conformity

Consult Instructions for Use

Use By

Manufacturer

Date of Manufacture

Contains Sufficient for <n> Tests

Keep Dry

Fragile, Handle with Care

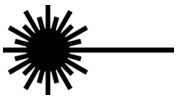
Caution, Consult Accompanying Documents

Biological Risks

Electric Shock Warning

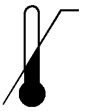
Radiation Warning

Potential Pinch Point Warning

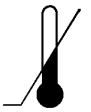


Laser

Temperature Limitation



Upper Limit of Temperature



Lower Limit of Temperature

IVD

In Vitro Diagnostic Medical Device

LOT

Batch Code

EC REP

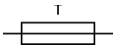
Authorized Representative in the European Community

REF

Catalog Number

Serial Number

Do Not Reuse



Fuse

Recyclable

Direct Current

Alternating Current

Both Direct and Alternating Current

Three-Phase Alternating Current

Earth (Ground) Terminal

Protective Conductor Terminal

Frame or Chassis Terminal

Equipotentiality

ON (Supply)

OFF (Supply)

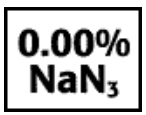
ON (Only for a Component of the System Equipment)

OFF (Only for a Component of the System Equipment)

Equipment Protected Throughout by Double Insulation or Reinforced Insulation (Equivalent to Class II of IEC 536)

Very Toxic

Corrosive



Sodium Azide

Irritant

Positive Control

Negative Control

Keep Away From Sunlight

Protect From Light

This Way Up

Do Not Stack

Humidity Limitations

Separate Collection for Waste Electrical and Electronic Equipment

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GN Product Information 1

Intended Use

The VITEK® 2 Gram-Negative identification card (GN) is intended for use with VITEK® 2 systems for the automated identification of most significant fermenting and non-fermenting gram-negative bacilli. The VITEK® 2 GN identification card is a single-use disposable. For a list of claimed species, see Organisms Identified by the GN Card on page 1-14.

Description

The GN card is based on established biochemical methods (1–12,14,15,17) and newly developed substrates measuring carbon source utilization, enzymatic activities, and resistance. There are 47 biochemical tests and one negative control well. The Decarboxylase Negative Control Well (well 52) is used as a baseline reference for the Decarboxylase test wells. Final results are available in approximately 10 hours or less.

For a list of well contents, see GN Well Contents on page 1-18.

Precautions

- For In Vitro Diagnostic Use Only.
- Suspensions not within the appropriate zone on the VITEK 2 DENSICHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- A Gram stain should be performed to determine an organism's Gram reaction and morphology prior to selecting which identification card to inoculate.

- The card performs as intended only when used in conjunction with VITEK® 2 systems.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Ensure that cards are filled properly and do not load any cards that are filled improperly. Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the vacuum fill.
- Give special consideration to specimen source and patient drug or antimicrobic regimen.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in microbial identification testing. Additional testing may be required (GN Supplemental Tests on page 1-20).

WARNING

All patient specimens and microbial cultures are potentially infectious and should be treated with universal precautions (13,16). It is suggested that highly pathogenic species such as *Brucella melitensis, Burkholderia mallei, Burkholderia pseudomallei, Escherichia coli O157, Francisella tularensis,* and *Yersinia pestis* be sent to your state health laboratory or other suitable reference laboratory for confirmation.

Storage and Handling

Upon receipt, store VITEK® 2 GN cards unopened in their original package liner at 2 °C to 8 °C.

Specimen Preparation

For specimen preparation information, see the Culture Requirements Table on page 1-24.

Materials

When used with VITEK® 2 instrumentation, the GN card is a complete system for routine identification testing of most significant fermenting and non-fermenting Gram-negative bacilli. Required materials are:

- VITEK® 2 GN Card
- VITEK 2 DENSICHEK™
- VITEK 2 DENSICHEK™ Power Adapter
- Lithium Battery of DENSICHEK
- DENSICHEK Calibrator
- VITEK® 2 Cassette
- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- 12 x 75 mm clear plastic (polystyrene) disposable test tubes
- Sterile sticks or swabs
- Appropriate agar medium (See Culture Requirements Table on page 1-24)

Optional accessories:

- Saline dispensers
- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Procedure

For product-specific information, see the Culture Requirements Table on page 1-24.

Note: *Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture is used for testing.*

1) Select isolated colonies from a primary plate, if culture requirements are met,
or
Subculture organism to be tested to appropriate agar medium and incubate accordingly.

2) Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).

3) Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare the homogenous organism suspension with a density equivalent to a McFarland No. 0.50 to 0.63 using a calibrated VITEK 2 DENSICHEK™.

Note: *Age of suspension must not exceed 30 minutes before inoculating card.*

4) Place the suspension tube and GN card in the cassette.

5) Refer to the User Manuals for the VITEK® 2 Instruments for instructions on data entry and how to load the cassette into the instrument.

6) Follow your local inspecting agency's guidelines for disposal of hazardous waste.

Results

Identification Analytical Techniques

The identification of an organism using the VITEK® 2 systems uses a methodology based on the characteristics of the data and knowledge about the organism and reactions being analyzed. Sufficient data have been collected from known strains to estimate the typical reactions of the claimed species to a set of discriminating biochemicals. If a unique identification pattern is not recognized, a list of possible organisms is given, or the strain is determined to be outside the scope of the database.

The printed lab report contains suggestions for any supplemental tests necessary to complete the identification. If the tests are not sufficient to complete the identification, then standard microbiology references and literature should be consulted.

Certain species may belong to a slashline (mixed) taxa identification. This occurs when the biopattern is the same for the taxa listed. Supplemental tests may be used to separate slashline taxa. The following species belong to GN slashline taxa.

Table 1-1: GN Slashline Taxa

Slashline Name	Species Belonging to the Slashline
Aeromonas hydrophila/caviae	*Aeromonas caviae* *Aeromonas hydrophila*
Brevundimonas diminuta/vesicularis	*Brevundimonas diminuta* *Brevundimonas vesicularis*
Burkholderia cepacia group	*Burkholderia cepacia* *Burkholderia multivorans* *Burkholderia stabilis* *Burkholderia vietnamiensis*
Moraxella group	*Moraxella lacunata* *Moraxella nonliquefaciens* *Moraxella osloensis*
Proteus vulgaris group*/Proteus penneri*	*Proteus penneri* *Proteus vulgaris* group
Salmonella group	*Salmonella enterica* ssp. *enterica* (formerly known as *Salmonella choleraesuis* ssp. *choleraesuis)* *Salmonella ser. Enteriditis* *Salmonella* ser. Paratyphi B *Salmonella* ser. Paratyphi C *Salmonella* spp. *Salmonella ser. Typhimurium*
Serratia liquefaciens group	*Serratia grimesii* *Serratia liquefaciens* *Serratia proteamaculans*
Shigella group	*Shigella boydii* *Shigella dysenteriae* *Shigella flexneri*
Yersinia enterocolitica group	*Yersinia aldovae* *Yersinia enterocolitica* *Yersinia frederiksenii* *Yersinia intermedia* *Yersinia kristensenii*

Identification Card Qualifying Messages

Table 1-2: Identification Card Qualifying Messages

ID Message Confidence Level	Choices	% Probability	Comments
Excellent	1	96 to 99	
Very Good	1	93 to 95	
Good	1	89 to 92	
Acceptable	1	85 to 88	
Low Discrimination	2 to 3	Sum of choices = 100; after resolution to one choice, percent probability reflects the number associated with selected choice.	2 to 3 taxa exhibit same biopattern. Separate by supplemental testing. Must resolve to mate with susceptibility card.
Unidentified Organism	> 3 or 0	n/a	Either > 3 taxa exhibit same biopattern or Very atypical biopattern. Does not correspond to any taxon in the database. Check Gram stain and purity.

Percent Probability

As part of the identification process, the software compares the test set of reactions to the expected set of reactions of each organism, or organism group, that can be identified by the product. A quantitative value, the percent probability, is calculated and relates to how well the observed reactions compare to the typical reactions of each organism. A perfect match between the test reaction pattern and the unique reaction pattern of a single organism, or organism group, would provide a percent probability of 99. When a perfect match is not obtained, it is still possible for the reaction pattern to be sufficiently close to that of an expected reaction pattern such that a clear decision can be provided about the organism identification. The range of percent probabilities in the one-choice case is 85 to 99. Values closer to 99 indicate a closer match to the typical pattern for the given organism.

When the reaction pattern is not sufficient to discriminate between two to three organisms, the percent probabilities reflect this ambiguity. The reported probability values indicate, relatively, the order in which the reaction pattern best corresponds to the listed possibilities. The order does not, however, suggest that the pattern match to one of the possible identifications is clearly superior to another. The probability characteristic of an overall sum of 100 is retained through the calculation process. After resolution to one choice, the probability characteristic of the single choice is retained.

Note: *(VITEK® 2 only) Results appear as **+**, **–**, or **?**. The **?** indicates a reaction too close to the threshold to be considered a clear positive or negative reaction.*

Note: *(VITEK® 2 Compact only) Results appear as **+**, **–**, (–) or (+). When a clear positive or a clear negative cannot be determined, the result may appear as a weak negative (–) which indicates a reaction slightly below the threshold or a weak positive (+) which indicates a reaction slightly above the threshold.*

Additional Information on Lab Report

Supplemental test — External test that allows the user to resolve a slashline or Low Discrimination identification.

Contraindicating test — Test result that is unusual for a reported taxon.

Notes Associated with Certain Taxa

Table 1-3: Notes Associated with Certain Taxa

Note	Taxa
Confirm by serological tests	*Escherichia coli* O157 *Francisella tularensis* *Salmonella* group *Salmonella* ser. *Gallinarum* *Salmonella* ser. Paratyphi A *Salmonella* ser. *Typhi* *Shigella* group *Shigella sonnei*
Highly pathogenic organism	*Brucella melitensis* *Burkholderia mallei* *Burkholderia pseudomallei* *Escherichia coli* O157 *Francisella tularensis* *Vibrio cholerae* *Yersinia pestis*

Notes Associated with Improperly Filled Card or Negative Profile (biopattern)

- For the case where the instrument determines that the card has not been filled:
  "Terminated card — no organism suspension detected."
- For the case where the time between two readings is higher than 40 minutes:
  "CARD ERROR — Missing data."
- For the case where there is a negative profile:
  "Organism with low reactivity biopattern — please check viability."
- When a biopattern is calculated for an unknown organism that is completely negative or consists of both negative tests and tests that fall within the uncertainty zone, the identification call will be "Nonreactive biopattern."

The following species could potentially trigger this note if a test was atypical or fell within the uncertainty zone:

Table 1-4: Non-Reactive Species

Acinetobacter haemolyticus
Acinetobacter lwoffii
Actinobacillus ureae
Aeromonas salmonicida
Brucella melitensis
Francisella tularensis
Methylobacterium spp.
Moraxella lacunata
Moraxella nonliquefaciens
Moraxella osloensis
Pasteurella multocida
Pseudomonas alcaligenes
Pseudomonas fluorescens
Pseudomonas stutzeri

Quality Control

Quality control organisms and their expected results are listed in the VITEK® 2 GN Quality Control Table and should be processed according to the procedure for test isolates outlined in this document. The GN card will identify the quality control organisms as one-choice, or within a low discrimination, or slashline identification. See the GN Quality Control Tables for more details.

Frequency of Testing

Currently, it is recommended that you use your most stringent inspecting agency's guidelines for frequency of identification product testing.

Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Product Information results.

If the results do not meet the criteria, subculture for purity and repeat test. If discrepant results are repeated, perform an alternate identification method.

Testing and Storage of QC Organisms

- Rehydrate organism according to the manufacturer's instructions.
- Use Trypticase Soy agar with 5% sheep blood (TSAB). Incubate aerobically at 35 °C to 37 °C for 18 to 24 hours.
- Check for purity. Perform second subculture for testing.

Storage Conditions

Short-Term Storage

1) Streak to a TSAB plate or slant.

2) Incubate for 24 hours at 35 °C to 37 °C.

3) Refrigerate at 2 °C to 8 °C for up to two weeks.

4) Subculture once as described above and use for QC.

Long-Term Storage

1) Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.

2) Freeze at –70 °C.

3) Subculture to TSAB twice before running QC.

Note: *Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.*

GN Quality Control Table

***Acinetobacter baumannii* ATCC® BAA-747**
***Enterobacter cloacae* ATCC 700323**
***Klebsiella oxytoca* ATCC 700324**
***Ochrobactrum anthropi* ATCC BAA-749**
***Proteus vulgaris* ATCC 6380**
***Shigella sonnei* ATCC 25931**
***Stenotrophomonas maltophilia* ATCC 17666**

The organisms below marked with an asterisk indicate additional quality control if required by local regulatory agencies.

Table 1-5: *QC Organism: *Acinetobacter baumannii* ATCC BAA-747

APPA	–	AGLTp	v	**BXYL**	–	SAC	–	**SUCT**	+	CMT	v
ADO	–	dGLU	+	**BAlap**	–	dTAG	–	**NAGA**	–	BGUR	–
PyrA	–	GGT	v	**ProA**	v	dTRE	–	**AGAL**	–	O129R	v
lARL	–	OFF	–	**LIP**	v	CIT	+	**PHOS**	–	GGAA	–
dCEL	v	BGLU	–	**PLE**	–	MNT	+	**GlyA**	v	lMLTa	v
BGAL	–	dMAL	–	**TyrA**	+	5KG	v	**ODC**	v	ELLM	–
H2S	–	dMAN	–	**URE**	v	lLATk	+	**LDC**	–	lLATa	v
BNAG	–	dMNE	+	**dSOR**	–	AGLU	–	**lHISa**	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 1-6: *QC Organism: *Enterobacter cloacae* ATCC 700323

APPA	–	AGLTp	–	**BXYL**	+	SAC	+	**SUCT**	v	CMT	–
ADO	+	dGLU	+	**BAlap**	–	dTAG	–	**NAGA**	+	BGUR	–
PyrA	–	GGT	+	**ProA**	v	dTRE	+	**AGAL**	v	O129R	+
lARL	–	OFF	+	**LIP**	v	CIT	+	**PHOS**	v	GGAA	–
dCEL	+	BGLU	–	**PLE**	+	MNT	+	**GlyA**	v	lMLTa	–
BGAL	+	dMAL	+	**TyrA**	v	5KG	–	**ODC**	+	ELLM	–
H2S	–	dMAN	+	**URE**	v	lLATk	v	**LDC**	–	lLATa	–
BNAG	+	dMNE	+	**dSOR**	+	AGLU	–	**lHISa**	–		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 1-7: Recommended QC Organism: *Klebsiella oxytoca* ATCC 700324

APPA	–	AGLTp	–	**BXYL**	–	SAC	+	**SUCT**	v	CMT	–
ADO	+	dGLU	+	**BAlap**	–	dTAG	+	**NAGA**	–	BGUR	–
PyrA	v	GGT	–	**ProA**	–	dTRE	+	**AGAL**	+	O129R	v
lARL	+	OFF	+	**LIP**	–	CIT	v	**PHOS**	+	GGAA	–
dCEL	+	BGLU	+	**PLE**	+	MNT	v	**GlyA**	–	lMLTa	v
BGAL	+	dMAL	+	**TyrA**	v	5KG	+ [1]	**ODC**	–	ELLM	v
H2S	–	dMAN	+	**URE**	+	lLATk	v	**LDC**	+	lLATa	v
BNAG	–	dMNE	+	**dSOR**	v	AGLU	–	**lHISa**	–		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

[1] Occasional negative reaction may occur with faster identification result.

Table 1-8: *QC Organism: *Ochrobactrum anthropi* ATCC BAA-749

APPA	v	AGLTp	v	**BXYL**	–	SAC	v	**SUCT**	v	CMT	v
ADO	v	dGLU	v	**BAlap**	v	dTAG	v	**NAGA**	–	BGUR	–
PyrA	+	GGT	v	**ProA**	+	dTRE	v	**AGAL**	–	O129R	–
lARL	–	OFF	–	**LIP**	v	CIT	v	**PHOS**	–	GGAA	v
dCEL	v	BGLU	v	**PLE**	v	MNT	–	**GlyA**	+	lMLTa	v
BGAL	–	dMAL	v	**TyrA**	+	5KG	–	**ODC**	–	ELLM	+
H2S	–	dMAN	–	**URE**	+	lLATk	v	**LDC**	–	lLATa	–
BNAG	–	dMNE	v	**dSOR**	–	AGLU	+	**lHISa**	–		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 1-9: *QC Organism: *Proteus vulgaris* ATCC 6380

APPA	–	AGLTp	–	**BXYL**	–	SAC	+	**SUCT**	v	CMT	v
ADO	–	dGLU	+	**BAlap**	–	dTAG	–	**NAGA**	–	BGUR	–
PyrA	–	GGT	v	**ProA**	v	dTRE	–	**AGAL**	–	O129R	v
lARL	–	OFF	v	**LIP**	v	CIT	v	**PHOS**	+	GGAA	v
dCEL	–	BGLU	+	**PLE**	v	MNT	–	**GlyA**	–	lMLTa	v
BGAL	–	dMAL	v	**TyrA**	v	5KG	–	**ODC**	–	ELLM	+
H2S	+	dMAN	–	**URE**	+	lLATk	v	**LDC**	–	lLATa	v
BNAG	–	dMNE	–	**dSOR**	–	AGLU	v	**lHISa**	–		

+ = 95% to 100% positive; v = 6% to 94% positive; - = 0% to 5% positive

Table 1-10: *QC Organism: *Shigella sonnei* ATCC 25931

APPA	–	AGLTp	-	**BXYL**	–	SAC	–	**SUCT**	v	CMT	+
ADO	–	dGLU	+	**BAlap**	–	dTAG	–	**NAGA**	–	BGUR	+
PyrA	–	GGT	–	**ProA**	v	dTRE	+	**AGAL**	v	O129R	v
lARL	–	OFF	v	**LIP**	v	CIT	–	**PHOS**	+	GGAA	–
dCEL	–	BGLU	–	**PLE**	–	MNT	–	**GlyA**	v	lMLTa	v
BGAL	+	dMAL	+	**TyrA**	+	5KG	–	**ODC**	+	ELLM	v
H2S	v	dMAN	+	**URE**	v	lLATk	v	**LDC**	–	lLATa	v
BNAG	–	dMNE	+	**dSOR**	–	AGLU	v	**lHISa**	–		

+ = 95% to 100% positive; v = 6% to 94% positive; - = 0% to 5% positive

Table 1-11: *QC Organism: *Stenotrophomonas maltophilia* ATCC 17666

APPA	+	AGLTp	–	**BXYL**	–	SAC	–	**SUCT**	v	CMT	–
ADO	–	dGLU	v	**BAlap**	–	dTAG	–	**NAGA**	–	BGUR	–
PyrA	–	GGT	v	**ProA**	+	dTRE	–	**AGAL**	–	O129R	–
lARL	–	OFF	–	**LIP**	+	CIT	v	**PHOS**	+	GGAA	+
dCEL	–	BGLU	v	**PLE**	–	MNT	v	**GlyA**	–	lMLTa	–
BGAL	–	dMAL	–	**TyrA**	v	5KG	–	**ODC**	–	ELLM	–
H2S	–	dMAN	–	**URE**	–	lLATk	v	**LDC**	–	lLATa	–
BNAG	v	dMNE	–	**dSOR**	–	AGLU	v	**lHISa**	–		

+ = 95% to 100% positive; v = 6% to 94% positive; - = 0% to 5% positive

Limitations

The VITEK® 2 GN card cannot be used with direct clinical samples or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

Newly described or rare species may not be included in the GN database. Selected species will be added as strains become available. Testing of unclaimed species may result in an unidentified result or a misidentification.

Performance Characteristics

In a recent multi-site clinical study*, the performance of the VITEK® 2 GN was evaluated using 562 clinical and stock isolates of both commonly and rarely observed species of gram-negative bacilli, including 153 non-fermentative strains. The reference identification was determined with api 20 E® and api® 20 NE identification kits. Overall, the VITEK® 2 GN correctly identified 96.8% of the isolates, including 6.4% low discrimination with the correct species listed. Misidentifications occurred at 3.0% and no identifications occurred at 0.2%.

Organisms Identified by the GN Card

Enterobacteriaceae

- *Buttiauxella agrestis*
- *Cedecea davisae*
- *Cedecea lapagei*
- *Citrobacter amalonaticus*
- *Citrobacter braakii*
- *Citrobacter farmeri*
- *Citrobacter freundii*
- *Citrobacter koseri*
- *Citrobacter sedlakii*
- *Citrobacter youngae*
- *Edwardsiella hoshinae*
- *Edwardsiella tarda*
- *Enterobacter aerogenes*
- *Enterobacter amnigenus* 1
- *Enterobacter amnigenus* 2

* Data on file at bioMérieux, Inc.

- *Enterobacter asburiae*
- *Enterobacter cancerogenus*
- *Enterobacter cloacae*
- *Enterobacter gergoviae*
- *Enterobacter intermedius*
- *Enterobacter sakazakii*
- *Escherichia coli*
- *Escherichia coli* O157
- *Escherichia fergusonii*
- *Escherichia hermannii*
- *Escherichia vulneris*
- *Ewingella americana*
- *Hafnia alvei*
- *Klebsiella oxytoca*
- *Klebsiella pneumoniae* ssp. *ozaenae*
- *Klebsiella pneumoniae* ssp. *pneumoniae*
- *Klebsiella pneumoniae* ssp. *rhinoscleromatis*
- *Kluyvera ascorbata*
- *Kluyvera cryocrescens*
- *Leclercia adecarboxylata*
- *Moellerella wisconsensis*
- *Morganella morganii* ssp. *morganii*
- *Morganella morganii* ssp. *sibonii*
- *Pantoea agglomerans*
- *Pantoea* spp.
- *Proteus mirabilis*
- *Proteus vulgaris* group*/Proteus penneri*
- *Providencia alcalifaciens*
- *Providencia rettgeri*
- *Providencia rustigianii*
- *Providencia stuartii*
- *Rahnella aquatilis*
- *Raoultella ornithinolytica*
- *Salmonella enterica* ssp. *arizonae* (formerly known as *Salmonella choleraesuis* ssp*. arizonae*)
- *Salmonella* group
- *Salmonella* ser. *Gallinarum*
- *Salmonella* ser. Paratyphi A
- *Salmonella* ser. *Typhi*
- *Serratia ficaria*
- *Serratia fonticola*
- *Serratia liquefaciens* group
- *Serratia marcescens*
- *Serratia odorifera*
- *Serratia plymuthica*
- *Serratia rubidaea*

- *Shigella* group
- *Shigella sonnei*
- *Yersinia enterocolitica* group
- *Yersinia pestis*
- *Yersinia pseudotuberculosis*
- *Yersinia ruckeri*
- *Yokenella regensburgei*

Non-*Enterobacteriaceae*

- *Achromobacter denitrificans* (formerly known as *Achromobacter xylosoxidans* ssp. *denitrificans*)
- *Achromobacter xylosoxidans (*formerly known as *Achromobacter xylosoxidans ssp. xylosoxidans)*
- *Acinetobacter baumannii*
- *Acinetobacter haemolyticus*
- *Acinetobacter junii*
- *Acinetobacter lwoffii*
- *Actinobacillus ureae*
- *Aeromonas hydrophila/Aeromonas caviae*
- *Aeromonas salmonicida*
- *Aeromonas sobria*
- *Aeromonas veronii*
- *Alcaligenes faecalis* ssp. *faecalis*
- *Bordetella bronchiseptica*
- *Bordetella trematum*
- *Brevundimonas diminuta / vesicularis*
- *Brucella melitensis*
- *Budvicia aquatica*
- *Burkholderia cepacia* group
- *Burkholderia gladioli*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- CDC group EF-4 *(Pasteurella)*
- *Chromobacterium violaceum*
- *Chryseobacterium gleum*
- *Chryseobacterium indologenes*
- *Chryseobacterium meningosepticum*
- *Comamonas testosteroni*
- *Delftia acidovorans*
- *Francisella tularensis*
- *Grimontia hollisae (*formerly known as *Vibrio hollisae)*
- *Mannheimia haemolytica*
- *Methylobacterium* spp.
- *Moraxella* group
- *Myroides* spp.

- *Ochrobactrum anthropi*
- *Oligella ureolytica*
- *Paracoccus yeeii* (formerly known as CDC group EO-2)
- *Pasteurella aerogenes*
- *Pasteurella multocida*
- *Pasteurella pneumotropica*
- *Photobacterium damselae*
- *Plesiomonas shigelloides*
- *Pseudomonas aeruginosa*
- *Pseudomonas alcaligenes*
- *Pseudomonas fluorescens*
- *Pseudomonas luteola*
- *Pseudomonas mendocina*
- *Pseudomonas oryzihabitans*
- *Pseudomonas pseudoalcaligenes*
- *Pseudomonas putida*
- *Pseudomonas stutzeri*
- *Ralstonia mannitolilytica*
- *Ralstonia pickettii*
- *Rhizobium radiobacter*
- *Shewanella putrefaciens*
- *Sphingobacterium multivorum*
- *Sphingobacterium spiritivorum*
- *Sphingobacterium thalpophilum*
- *Sphingomonas paucimobilis*
- *Stenotrophomonas maltophilia*
- *Vibrio alginolyticus*
- *Vibrio cholerae*
- *Vibrio fluvialis*
- *Vibrio metschnikovii*
- *Vibrio mimicus*
- *Vibrio parahaemolyticus*
- *Vibrio vulnificus*
- *Wautersia paucula* (formerly known as *Ralstonia paucula*)

Highly Pathogenic Organisms

- *Brucella melitensis*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- *Escherichia coli* 0157
- *Francisella tularensis*
- *Vibrio cholerae*
- *Yersinia pestis*

GN Well Contents

Table 1-12: GN Well Contents

Well	Test	Mnemonic	Amount/Well
2	Ala-Phe-Pro-ARYLAMIDASE	APPA	0.0384 mg
3	ADONITOL	ADO	0.1875 mg
4	L-Pyrrolydonyl-ARYLAMIDASE	PyrA	0.018 mg
5	L-ARABITOL	lARL	0.3 mg
7	D-CELLOBIOSE	dCEL	0.3 mg
9	BETA-GALACTOSIDASE	BGAL	0.036 mg
10	H2S PRODUCTION	H2S	0.0024 mg
11	BETA-N-ACETYL-GLUCOSAMINIDASE	BNAG	0.0408 mg
12	Glutamyl Arylamidase pNA	AGLTp	0.0324 mg
13	D-GLUCOSE	dGLU	0.3 mg
14	GAMMA-GLUTAMYL-TRANSFERASE	GGT	0.0228 mg
15	FERMENTATION/ GLUCOSE	OFF	0.45 mg
17	BETA-GLUCOSIDASE	BGLU	0.036 mg
18	D-MALTOSE	dMAL	0.3 mg
19	D-MANNITOL	dMAN	0.1875 mg
20	D-MANNOSE	dMNE	0.3 mg
21	BETA-XYLOSIDASE	BXYL	0.0324 mg
22	BETA-Alanine arylamidase pNA	BAlap	0.0174 mg
23	L-Proline ARYLAMIDASE	ProA	0.0234 mg
26	LIPASE	LIP	0.0192 mg
27	PALATINOSE	PLE	0.3 mg
29	Tyrosine ARYLAMIDASE	TyrA	0.0276 mg
31	UREASE	URE	0.15 mg
32	D-SORBITOL	dSOR	0.1875 mg
33	SACCHAROSE/SUCROSE	SAC	0.3 mg
34	D-TAGATOSE	dTAG	0.3 mg
35	D-TREHALOSE	dTRE	0.3 mg
36	CITRATE (SODIUM)	CIT	0.054 mg
37	MALONATE	MNT	0.15 mg
39	5-KETO-D-GLUCONATE	5KG	0.3 mg

Table 1-12: GN Well Contents

Well	Test	Mnemonic	Amount/Well
40	L-LACTATE alkalinisation	lLATk	0.15 mg
41	ALPHA-GLUCOSIDASE	AGLU	0.036 mg
42	SUCCINATE alkalinisation	SUCT	0.15 mg
43	Beta-N-ACETYL-GALACTOSAMINIDASE	NAGA	0.0306 mg
44	ALPHA-GALACTOSIDASE	AGAL	0.036 mg
45	PHOSPHATASE	PHOS	0.0504 mg
46	Glycine ARYLAMIDASE	GlyA	0.012 mg
47	ORNITHINE DECARBOXYLASE	ODC	0.3 mg
48	LYSINE DECARBOXYLASE	LDC	0.15 mg
52	DECARBOXYLASE BASE	0DEC	NA
53	L-HISTIDINE assimilation	lHlSa	0.087 mg
56	COURMARATE	CMT	0.126 mg
57	BETA-GLUCORONIDASE	BGUR	0.0378 mg
58	O/129 RESISTANCE (comp.vibrio.)	O129R	0.0105 mg
59	Glu-Gly-Arg-ARYLAMIDASE	GGAA	0.0576 mg
61	L-MALATE assimilation	lMLTa	0.042 mg
62	ELLMAN	ELLM	0.03 mg
64	L-LACTATE assimilation	lLATa	0.186 mg

Note: *Other well numbers between 1 and 64 not designated in this table are empty.*

GN Supplemental Tests

Table 1-13: GN Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
41C	GROWTH AT 41 °C	Ability of certain species to grow at 41 °C		10
42C	GROWTH AT 42 °C	Ability of certain species to grow at 42 °C.		11
ADONITOL dCELLOB, dMALTOSE, dMANNITOL, dMELIBIOSE, dTREHALOSE, lRHAMNOSE, SACCHAROSE	ADONITOL acidification D-CELLOBIOSE acidification, D-MALTOSE acidification, D-MANNITOL acidification, D-MELIBIOSE acidification, D-TREHALOSE acidification, L-RHAMNOSE acidification, SACCHAROSE/SUCROSE acidification	Acidification of carbon source observed with pH indicator (e.g., phenol red, bromocresol purple, etc.).	Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	4,6,8,9,11, 12,17
dFRUCTOSEa, dGLUCOSEa, dMANNITOLa, dMELa, lSORBOSEa,	D-FRUCTOSE assimilation, D-GLUCOSE assimilation, D-MANNITOL assimilation, D-MELIBIOSE assimilation, L-SORBOSE assimilation,	Capability of organisms to grow using a specific sole carbon source.		2,3,9,10
Arg.hydr.	ARGININE dihydrolase	Hydrolysis of arginine releases an amine resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).		6,8,9,10,11, 15,17
B-HEM	BETA HEMOLYSIS	Certain species possess hemolysins that give a transparent zone around colonies on blood-based agar.		5,11,17

Table 1-13: GN Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
DNAse	DNAse test	Ability of certain species to produce DNAse resulting in the degradation of DNA.		9,11,17
ESCULIN	ESCULIN hydrolysis	Hydrolysis of esculin forms esculetin that produces a black pigment in the presence of iron salts.		8,9,11,17
GELATIN	GELATIN hydrolysis	Mediated by a gelatinase enzyme, a positive reaction is observed by liquefaction of the gelatin substrate.		5,10,11,14
IND	INDOLE	Ability of certain species to split indole from tryptophan detected by a colored product revealed with a specific reagent (e.g., Kovacs, Ehrlich's, DMAC reagents, etc.).		6,8,9,11,17
Lysine dec.	Lysine decarboxylase	Hydrolysis of lysine releases an amine resulting in alkalinization of the medium observed with a pH indicator (e.g., purple color formation in the presence of bromcresol purple).	Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	12
MOB	MOTILITY	Test for motility using hanging drop procedure or saline mount.	Bacterial motility can be observed by placing a drop of bacterial suspension on a slide and viewing it under a microscope.	3,8,9,11,15, 17

Table 1-13: GN Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
NAT	SODIUM-ACETATE alkalinisation	Ability of certain species to utilize acetate as a sole source of carbon		18
NO2 NO3 NO3 –-> N2	NITRITE REDUCTION NITRATE REDUCTION NITROGEN PRODUCTION FROM NO3	Test for the ability to reduce nitrate to nitrogen gas (NO2), nitrate to nitrite and/ or nitrogen gas (NO3) or nitrogen gas from nitrate (NO3 –-> N2).		6,11,18
NaCl 0%, NaCl 6%	GROWTH IN 0% NaCl GROWTH IN 6% NaCl	Ability of certain species to grow in the presence or absence of 6.0% NaCl.		4,11
O/129 R	O/129 RESISTANCE	Ability of certain species to grow in the presence of the vibriostatic compound O/129.	Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	4,7
ONPG	BETA_GALACTOSIDASE	Presence of beta-galactosidase cleaves o-nitrophenol-beta-D-galcatopyranoside to produce a yellow colored product.		4,8,9,11
Ornith.dec	Ornithine decarboxylase	Hydrolysis of ornithine releases an amine resulting in alkalinization of the medium observed with a pH indicator (e.g., purple color formation in the presence of bromocresol purple).	Some tests also appear on the GN card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	4,6,9,11,17

Table 1-13: GN Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
OX	OXIDASE	Detection of the presence of cytochrome C.	Characteristic useful in identifying many species of non-fermenters. All members of *Enterobacteriaceae* are oxidase-negative.	6,8,9,10,11, 15,17
PURPLE	PURPLE PIGMENT	Ability of certain species to produce purple colonies on non-differential media.	Characteristic of *Chromobacterium violaceum.*	11
PYOCYANIN PYOVERDIN	PYOCYANIN pigment PYOVERDIN pigment	Ability of species to produce blue pigment (pyocyanin) or fluorescent pigment (pyoverdin).	Presence of both pyocyanin and pyoverdin is characteristic of *Pseudomonas aeruginosa* producing greenish fluorescent colonies.	1,11
UREASE	Urease	Hydrolysis of urea releases ammonia resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).		6,8,9,11,15, 17
VP	VOGES PROSKAUER	Ability of some species to produce acetoin from glucose fermentation.		11,9,8,15
YELLOW	YELLOW PIGMENT	Ability of certain species to produce yellow pigmented colonies on non-differential media.		8,9,11,17

Culture Requirements Table

Table 1-14: Culture Requirements

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	Inoculum Density	Dilution for AST	Age of Suspension Before Loading Instrument
GN	TSA[1] CBA[1] MAC[1] BCP CET CLED CHOC CHOC PVX CHBA CNT CPS-ID3 DENA DRIG HEK TSAHB TSAB TSAL VRBG XLD	18 to 24 hours	35 °C to 37 °C Aerobic, non-CO_2	0.50 to 0.63 McFarland Standard	N/A	≤30 minutes
GN and AST GN pair	CBA[1] MAC[1] TSAB	18 to 24 hours	35 °C to 37 °C Aerobic, non-CO_2	0.50 to 0.63 McFarland Standard	145 µL in 3.0 mL saline	≤ 30 minutes

[1]These media were used in the identification product database development and will give optimal performance.

Culture Requirements Table — Media Abbreviations

BCP	=	Brom Cresol Purple agar
CBA	=	Columbia agar with 5% sheep blood
CET	=	Cetrimide agar
CHBA	=	Columbia horse blood agar
CHOC	=	Chocolate agar
CHOC PVX	=	Chocolate Polyvitex
CLED	=	Cystine Lactose Electrolyte Deficient agar
CNT	=	Count-TACT
CPS-ID3	=	CPS-ID3
DENA	=	DE Neutralizing agar
DRIG	=	Drigalski agar
HEK	=	Hektoen agar
MAC	=	MacConkey agar
TSA	=	Trypticase soy agar
TSAB	=	Trypticase soy agar with 5% sheep blood
TSAHB	=	Trypticase soy agar with 5% horse blood
TSAL	=	TSA with Lecithin and P80
VRBG	=	Violet Red Bile Glucose agar
XLD	=	Xylose Lysine Desoxycholate

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bioMérieux, Inc.

Use this Online Product Information with VITEK® 2 Product No. 21341.

bioMérieux, Inc.
Box 15969,
Durham, North Carolina 27704-0969 USA
tel. (1) 800.682.2666

EC REP

bioMérieux sa
au capital de 11 879 045 Euros
673 620 399 RCS LYON
69280 Marcy-l'Etoile/ France
tel. (33) 04 78 87 20 00
fax (33) 04 78 87 20 90
http://www.biomerieux.com

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GP Product Information 2

Intended Use

The VITEK® 2 Gram-Positive identification card (GP) is intended for use with VITEK® 2 systems for the automated identification of most significant gram-positive organisms. The VITEK® 2 GP identification card is a single-use disposable. For a list of claimed species, See Organisms Identified by the GP Card, starting on page 2-13.

Description

The GP identification card is based on established biochemical methods (2, 3, 5-9, 11, 16-19, 21, 24, 25, 27, 28) and newly developed substrates. There are 43 biochemical tests measuring carbon source utilization, enzymatic activities and resistance. Final identification results are available in approximately eight hours or less.

For a list of well contents, See GP Well Contents on page 2-16.

Precautions

- For In Vitro Diagnostic Use Only.
- Suspensions not within the appropriate zone on the VITEK 2 DENSICHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Do not use powdered gloves. Powder may interfere with the optics.
- Allow the card to come to room temperature before opening the package liner.
- Use of a culture medium other than the recommended types must be validated by the customer laboratory for acceptable performance.
- A Gram stain should be performed to determine an organism's Gram reaction and morphology prior to selecting which identification card to inoculate.

- The card performs as intended only when used in conjunction with VITEK® 2 systems.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Ensure that cards are filled properly and do not load any cards that are filled improperly. Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the vacuum fill.
- Give special consideration to specimen source and patient drug or antimicrobic regimen.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in microbial identification testing. Additional testing may be required (GP Supplemental Tests on page 2-18).

WARNING

All patient specimens and microbial cultures are potentially infectious and should be treated with universal precautions (23,26).

Storage and Handling

Upon receipt, store VITEK® 2 GP cards unopened in their original package liner at 2 °C to 8 °C.

Specimen Preparation

For specimen preparation information, see the Culture Requirements Table on page 2-22.

Materials

When used with VITEK® 2 instrumentation, the GP card is a complete system for routine identification testing of most significant Gram-positive organisms. Required materials are:

- VITEK® 2 GP Card
- VITEK 2 DENSICHEK™
- VITEK 2 DENSICHEK™ Power Adapter
- Lithium Battery for DENSICHEK
- DENSICHEK Calibrator
- VITEK® 2 Cassette
- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- 12 x 75 mm clear plastic (polystyrene) disposable test tubes
- Sterile sticks or swabs
- Appropriate agar medium (See Culture Requirements Table on page 2-22.)

Optional accessories:

- Saline Dispensers
- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Procedure

For product-specific information, see the Culture Requirements Table on page 2-22.

Note: *Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity plate be done to ensure that a pure culture was used for testing.*

1) Select isolated colonies from a primary plate, if culture requirements are met,
or
Subculture organism to be tested to appropriate agar medium and incubate accordingly.

2) Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).

3) Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare a homogenous suspension of the organism with a density equivalent to a McFarland No. 0.50 to 0.63 using a calibrated VITEK 2 DENSICHEK™.

Note: *Age of suspension must not exceed 30 minutes before inoculating card.*

4) Place the suspension tube and GP card in the cassette.

5) Refer to the User Manuals for the VITEK® 2 Instruments for instructions on data entry and how to load the cassette into the instrument.

6) Follow your local regulatory agency's guidelines for disposal of hazardous waste.

Results

Identification Analytical Techniques

The identification of an organism using the VITEK® 2 systems uses a methodology based on the characteristics of the data and knowledge about the organism and reactions being analyzed. Sufficient data have been collected from known strains to estimate the typical reactions of the claimed species to a set of discriminating biochemicals. If a unique identification pattern is not recognized, a list of possible organisms is given, or the strain is determined to be outside the scope of the database.

The printed lab report contains suggestions for any supplemental test necessary to complete the identification. If the tests are not sufficient to complete the identification, then standard microbiology references and literature should be consulted.

Certain species may belong to slashline (mixed) taxa. This occurs when the biopattern is the same for the taxa listed. Supplemental tests may be used to separate slashline taxa. The following species belong to slashline taxa.

Table 2-1: Slashline Taxa

Slashline Name	Species Belonging to the Slashline
Dermacoccus nishinomiyaensis/Kytococcus sedentarius	*Dermacoccus nishinomiyaensis* *Kytococcus sedentarius*
Listeria ivanovii	*Listeria ivanovii* ssp. *ivanovii* *Listeria ivanovii* ssp. *londoniensis*
Micrococcus luteus/lylae	*Micrococcus luteus* *Micrococcus lylae*
Staphylococcus capitis	*Staphylococcus capitis* ssp. *capitis* *Staphylococcus capitis* ssp. *ureolyticus*

Table 2-1: Slashline Taxa

Staphylococcus hominis	*Staphylococcus hominis* ssp. *hominis* *Staphylococcus hominis* ssp. *novobiosepticus*
Streptococcus infantarius ssp. *coli*/ *Streptococcus bovis*	*Streptococcus bovis* *Streptococcus infantarius* ssp. *coli*
Streptococcus mitis/Streptococcus oralis	*Streptococcus mitis* *Streptococcus oralis*

Identification Card Qualifying Messages

Table 2-2: Identification Card Qualifying Messages

ID Message Confidence Level	Choices	% Probability	Comments
Excellent	1	96 to 99	
Very Good	1	93 to 95	
Good	1	89 to 92	
Acceptable	1	85 to 88	
Low Discrimination	2 to 3	Sum of choices = 100; after resolution to one choice, percent probability reflects the number associated with selected choice.	2 to 3 taxa exhibit same biopattern. Separate by supplemental testing. Must resolve to mate with susceptibility card.
Unidentified Organism	> 3 or 0	n/a	Either > 3 taxa exhibit same biopattern or Very atypical biopattern. Does not correspond to any taxon in the database. Check Gram stain and purity.

Percent Probability

As part of the identification process, the software compares the test set of reactions to the expected set of reactions of each organism, or organism group, that can be identified by the product. A quantitative value, the percent probability, is calculated and relates to how well the observed reactions compare to the typical reactions of each organism. A perfect match between

the test reaction pattern and the unique reaction pattern of a single organism, or organism group, would provide a percent probability of 99. When a perfect match is not obtained, it is still possible for the reaction pattern to be sufficiently close to that of an expected reaction pattern such that a clear decision can be provided about the organism identification. The range of percent probabilities in the one-choice case is 85 to 99. Values closer to 99 indicate a closer match to the typical pattern for the given organism.

When the reaction pattern is not sufficient to discriminate between two to three organisms, the percent probabilities reflect this ambiguity. The reported probability values indicate, relatively, the order in which the reaction pattern best corresponds to the listed possibilities. The order does not, however, suggest that the pattern match to one of the possible identifications is clearly superior to another. The probability characteristic of an overall sum of 100 is retained through the calculation process. After resolution to one choice, the probability characteristic of the single choice is retained.

Note: *(VITEK® 2 only) Results appear as +, –, or **?**. The **?** indicates a reaction too close to the threshold to be considered a clear positive or negative reaction.*

Note: *(VITEK® 2 Compact only) Results appear as +, –, (–) or (+). When a clear positive or a clear negative cannot be determined, the result may appear as a weak negative (–) which indicates a reaction slightly below the threshold or a weak positive (+) which indicates a reaction slightly above the threshold.*

Additional Information on the Lab Report

Supplemental test — External test which allows the user to resolve slashline or low discrimination identification.

Contraindicating test — Test result that is unusual for a reported taxon.

Notes associated with certain taxa

Table 2-3: Notes associated with certain taxa

Note	Taxon
Highly pathogenic organism, check Camp test and beta hemolysis.	*Listeria monocytogenes*
Possibility of *Staphylococcus pasteuri* if yellow pigmented	*Staphylococcus warneri*

Table 2-3: Notes associated with certain taxa

Possibility of *Enterococcus villorum* if veterinary	*Enterococcus durans*

Notes associated with an improperly filled card or with a negative profile (biopattern)

- For the case where the instrument determines that the card has not been filled:
  "Terminated card—no organism suspension detected."
- For the case where the time between two readings is higher than 40 minutes:
  "CARD ERROR—Missing data."
- For the case where there is a negative profile:
  "Organism with low reactivity biopattern—please check viability."
- When a biopattern is calculated for an unknown organism that is completely negative or consists of both negative tests and tests that fall within the uncertainty zone, the identification call will be "Nonreactive biopattern."

The following species could potentially trigger this note if a test was atypical or fell within the uncertainty zone:

Table 2-4: Non-Reactive Species

Alloiococcus otitis
Dermacoccus nishinomiyaensis
Dolosigranulum pigrum
Gemella bergeri
Kocuria rosea
Kocuria varians
Kytococcus sedentarius
Leuconostoc mesenteroides ssp. *cremoris*
Micrococcus lylae
Staphylococcus auricularis
Streptococcus pluranimalium

Quality Control

Quality control organisms and their expected results are listed in the VITEK® 2 GP Quality Control Table and should be processed according to the procedure for test isolates outlined in this document. The GP card will identify the quality control organisms as one-choice, or within a low discrimination, or slashline. See GP Quality Control Table on page 2-9 for more details.

Frequency of Testing

Currently, it is recommended that you use your most stringent inspecting agency's guidelines for frequency of identification product testing.

Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Online Product Information results.

If the results do not meet the criteria, subculture for purity and repeat test. If discrepant results are repeated, perform an alternate identification method.

Testing and Storage of QC Organisms

- Rehydrate organism according to the manufacturer's instructions.
- Use Trypticase Soy with 5% sheep blood agar (TSAB) and incubate at 35 °C to 37 °C in aerobic 5% to10% CO_2 for approximately 18 to 24 hours.
- Check for purity. Perform second subculture for testing.

Storage Conditions

Short-Term Storage

1) Subculture to a TSAB plate or slant.

2) Incubate for 24 hours at 35 °C to 37 °C.

3) Refrigerate at 2 °C to 8 °C for up to two weeks.

4) Subculture once as described above and use for QC.

Long-Term Storage

1) Make a heavy suspension in Tryptic Soy Broth with 15% glycerol.

2) Freeze at -70 °C

3) Subculture to TSAB twice before running QC.

Note: *Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.*

GP Quality Control Table

***Enterococcus casseliflavus* ATCC® 700327**
***Kocuria kristinae* ATCC BAA-752**
***Listeria monocytogenes* ATCC BAA-751**
***Staphylococcus aureus* ssp. *aureus* ATCC 29213**
***Staphylococcus saprophyticus* ATCC BAA-750**
***Staphylococcus sciuri* ATCC 29061**
***Streptococcus equi* ssp. *zooepidemicus* ATCC 43079**
***Streptococcus thermophilus* ATCC 19258**

The organisms below marked with an asterisk indicate additional quality control if required by local regulatory agencies.

Table 2-5: *QC Organism: *Enterococcus casseliflavus* ATCC 700327

AMY	+	CDEX	–	**BGURr**	–	URE	–	**dMAL**	+	PUL	–
PIPLC	–	AspA	+ [1]	**AGAL**	+	POLYB	v	**BACl**	+	dRAF	+
dXYL	+	BGAR	+	**PyrA**	+	dGAL	+	**NOVO**	+	O129R	v
ADH1	v	AMAN	v	**BGUR**	–	dRIB	+	**NC6.5**	+	SAL	+
BGAL	+	PHOS	–	**AlaA**	v	lLATk	–	**dMAN**	+	SAC	+
AGLU	v	LeuA	v	**TyrA**	v	LAC	+	**dMNE**	+	dTRE	+
APPA	v	ProA	–	**dSOR**	v	NAG	+	**MBdG**	+	ADH2s	v
										OPTO	+

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

[1] Occasional negative reaction may occur with faster identification result.

Table 2-6: *QC Organism: *Kocuria kristinae* ATCC BAA-752

AMY	–	CDEX	–	**BGURr**	–	URE	–	**dMAL**	v	PUL	–
PIPLC	–	AspA	–	**AGAL**	–	POLYB	v	**BACl**	v	dRAF	–
dXYL	–	BGAR	–	**PyrA**	v	dGAL	–	**NOVO**	–	O129R	v
ADH1	v	AMAN	–	**BGUR**	–	dRIB	–	**NC6.5**	+	SAL	v
BGAL	–	PHOS	–	**AlaA**	+	lLATk	v	**dMAN**	–	SAC	+
AGLU	+	LeuA	+	**TyrA**	v	LAC	–	**dMNE**	+	dTRE	v
APPA	v	ProA	+	**dSOR**	v	NAG	–	**MBdG**	–	ADH2s	–
										OPTO	+

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 2-7: *QC Organism: *Listeria monocytogenes* ATCC BAA-751

AMY	+	CDEX	+	**BGURr**	–	URE	–	**dMAL**	+	PUL	–
PIPLC	v	AspA	v	**AGAL**	–	POLYB	+	**BACl**	+	dRAF	–
dXYL	–	BGAR	–	**PyrA**	–	dGAL	–	**NOVO**	v	O129R	+
ADH1	–	AMAN	+	**BGUR**	–	dRIB	–	**NC6.5**	+	SAL	+
BGAL	–	PHOS	–	**AlaA**	v	lLATk	–	**dMAN**	–	SAC	–
AGLU	+	LeuA	v	**TyrA**	+	LAC	v	**dMNE**	+	dTRE	+
APPA	v	ProA	–	**dSOR**	–	NAG	+	**MBdG**	+	ADH2s	–
										OPTO	+

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 2-8: *QC Organism: *Staphylococcus aureus* ssp. *aureus* ATCC 29213

AMY	–	CDEX	–	**BGURr**	–	URE	–	**dMAL**	+	PUL	–
PIPLC	–	AspA	–	**AGAL**	–	POLYB	v	**BACl**	+	dRAF	–
dXYL	–	BGAR	–	**PyrA**	+	dGAL	v	**NOVO**	v	O129R	+
ADH1	+	AMAN	–	**BGUR**	–	dRIB	v	**NC6.5**	+	SAL	–
BGAL	v	PHOS	+	**AlaA**	–	lLATk	+	**dMAN**	+	SAC	+
AGLU	v	LeuA	v	**TyrA**	–	LAC	v	**dMNE**	+	dTRE	–
APPA	–	ProA	–	**dSOR**	–	NAG	v	**MBdG**	+	ADH2s	v
										OPTO	+

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 2-9: *QC Organism: *Staphylococcus saprophyticus* ATCC BAA-750

AMY	–	CDEX	–	**BGURr**	–	URE	+	**dMAL**	+	PUL	–
PIPLC	–	AspA	–	**AGAL**	–	POLYB	–	**BACl**	+	dRAF	–
dXYL	–	BGAR	–	**PyrA**	v	dGAL	v	**NOVO**	+	O129R	v
ADH1	v	AMAN	–	**BGUR**	–	dRIB	v	**NC6.5**	+	SAL	–
BGAL	+	PHOS	v	**AlaA**	–	lLATk	v	**dMAN**	+	SAC	+
AGLU	v	LeuA	–	**TyrA**	–	LAC	+	**dMNE**	v	dTRE	+
APPA	v	ProA	–	**dSOR**	–	NAG	v	**MBdG**	–	ADH2s	–
										OPTO	+

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 2-10: *QC Organism: *Staphylococcus sciuri* ATCC 29061

AMY	+	CDEX	–	**BGURr**	+	URE	–	**dMAL**	+	PUL	–
PIPLC	–	AspA	–	**AGAL**	–	POLYB	–	**BACl**	v	dRAF	–
dXYL	–	BGAR	v	**PyrA**	–	dGAL	v	**NOVO**	v	O129R	v
ADH1	+	AMAN	v	**BGUR**	+	dRIB	v	**NC6.5**	+	SAL	+
BGAL	v	PHOS	+	**AlaA**	v	lLATk	v	**dMAN**	+	SAC	+
AGLU	v	LeuA	v	**TyrA**	v	LAC	–	**dMNE**	+	dTRE	+
APPA	–	ProA	–	**dSOR**	v	NAG	v	**MBdG**	+	ADH2s	–
										OPTO	+

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 2-11: Recommended QC Organism: *Streptococcus equi* ssp. *zooepidemicus* ATCC 43079

AMY	–	CDEX	v	**BGURr**	v	URE	–	**dMAL**	+	PUL	+
PIPLC	–	AspA	–	**AGAL**	–	POLYB	v	**BACl**	v	dRAF	–
dXYL	–	BGAR	–	**PyrA**	–	dGAL	+	**NOVO**	+	O129R	v
ADH1	+	AMAN	–	**BGUR**	v	dRIB	v	**NC6.5**	v	SAL	v
BGAL	v	PHOS	+	**AlaA**	+	lLATk	–	**dMAN**	v	SAC	+
AGLU	v	LeuA	+	**TyrA**	+	LAC	v	**dMNE**	+	dTRE	–
APPA	v	ProA	v	**dSOR**	v	NAG	+	**MBdG**	v	ADH2s	v
										OPTO	+

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 2-12: *QC Organism: *Streptococcus thermophilus* ATCC 19258

AMY	**–**	CDEX	–	**BGURr**	**–**	URE	v	**dMAL**	**–**	PUL	–
PIPLC	**–**	AspA	–	**AGAL**	**–**	POLYB	v	**BACl**	**v**	dRAF	v
dXYL	**–**	BGAR	+	**PyrA**	**–**	dGAL	–	**NOVO**	**+**	O129R	+
ADH1	**–**	AMAN	–	**BGUR**	**–**	dRIB	–	**NC6.5**	**–**	SAL	–
BGAL	**+**	PHOS	–	**AlaA**	**+**	lLATk	–	**dMAN**	**–**	SAC	+
AGLU	**–**	LeuA	+	**TyrA**	**+**	LAC	+	**dMNE**	**v**	dTRE	–
APPA	**+**	ProA	v	**dSOR**	**–**	NAG	–	**MBdG**	**–**	ADH2s	–
										OPTO	+

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Limitations

The VITEK® 2 GP card cannot be used with direct clinical samples or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

Newly described or rare species that are found occasionally may not be included in the GP database. Selected species will be added as strains become available. Testing of unclaimed species may result in an unidentified result or a misidentification.

Performance Characteristics

In a recent multi-site clinical study*, the performance of the VITEK® 2 GP was evaluated using 457 clinical and stock isolates of both commonly and rarely observed species of gram-positive cocci. The reference identification was determined with api® STAPH and api® 20 STREP identification kits. Overall, the VITEK® 2 GP correctly identified 96.5% of the isolates, including 2.2% low discrimination with the correct species listed. Misidentifications occurred at 3.3% and no identifications occurred at 0.2%.

Organisms Identified by the GP Card

- *Abiotrophia defectiva*
- *Aerococcus urinae*
- *Aerococcus viridans*
- *Alloiococcus otitis*
- *Dermacoccus nishinomiyaensis/Kytococcus sedentarius*
- *Enterococcus avium*
- *Enterococcus casseliflavus*
- *Enterococcus cecorum*
- *Enterococcus columbae*
- *Enterococcus durans*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Enterococcus gallinarum*
- *Enterococcus hirae*
- *Enterococcus raffinosus*
- *Enterococcus saccharolyticus*

* Data on file at bioMérieux, Inc.

- *Erysipelothrix rhusiopahiae*
- *Facklamia hominis*
- *Gardnerella vaginalis*
- *Gemella bergeri*
- *Gemella haemolysans*
- *Gemella morbillorum*
- *Gemella sanguinis*
- *Globicatella sanguinis*
- *Globicatella sulfidifaciens*
- *Granulicatella adiacens*
- *Granulicatella elegans*
- *Helcococcus kunziii*
- *Kocuria kristinae*
- *Kocuria rosea*
- *Kocuria varians*
- *Lactococcus garvieae*
- *Lactococcus lactis* ssp. *cremoris*
- *Lactococcus lactis* ssp. *lactis*
- *Lactococcus raffinolactis*
- *Leuconostoc citreum*
- *Leuconostoc lactis*
- *Leuconostoc mesenteroides* ssp. *cremoris*
- *Leuconostoc mesenteroides* ssp. *dextranicum*
- *Leuconostoc mesenteroides* ssp. *mesenteroides*
- *Leuconostoc pseudomesenteroides*
- *Listeria grayi*
- *Listeria innocua*
- *Listeria ivanovii*
- *Listeria monocytogenes*
- *Listeria seeligeri*
- *Listeria welshimeri*
- *Micrococcus luteus/lylae*
- *Pediococcus acidilactici*
- *Pediococcus pentosaceus*
- *Rothia mucilaginosa*
- *Staphylococcus arlettae*
- *Staphylococcus aureus* *
- *Staphylococcus auricularis*
- *Staphylococcus capitis*
- *Staphylococcus caprae*
- *Staphylococcus carnosus* ssp. *carnosus*
- *Staphylococcus chromogenes*
- *Staphylococcus cohnii* ssp. *cohnii*
- *Staphylococcus cohnii* ssp. *urealyticus (*formerly known as *Staphylococcus cohnii* ssp. *urealyticum)*
- *Staphylococcus epidermidis*

- *Staphylococcus equorum*
- *Staphylococcus gallinarum*
- *Staphylococcus haemolyticus*
- *Staphylococcus hominis*
- *Staphylococcus hyicus*
- *Staphylococcus intermedius*
- *Staphylococcus kloosii*
- *Staphylococcus lentus*
- *Staphylococcus lugdunensis*
- *Staphylococcus saprophyticus*
- *Staphylococcus schleiferi*
- *Staphylococcus sciuri*
- *Staphylococcus simulans*
- *Staphylococcus vitulinus*
- *Staphylococcus warneri*
- *Staphylococcus xylosus*
- *Streptococcus agalactiae*
- *Streptococcus alactolyticus*
- *Streptococcus anginosus*
- *Streptococcus canis*
- *Streptococcus constellatus* ssp. *constellatus*
- *Streptococcus constellatus* ssp. *pharyngis*
- *Streptococcus cristatus*
- *Streptococcus downei*
- *Streptococcus dysgalactiae* ssp. *dysgalactiae*
- *Streptococcus dysgalactiae* ssp. *equisimilis*
- *Streptococcus equi* ssp. *equi*
- *Streptococcus equi* ssp. *zooepidemicus*
- *Streptococcus equinus*
- *Streptococcus gallolyticus* ssp. *gallolyticus*
- *Streptococcus gallolyticus* ssp. *pasteurianus*
- *Streptococcus gordonii*
- *Streptococcus hyointestinalis*
- *Streptococcus infantarius* ssp. *infantarius*
- *Streptococcus infantarius* ssp. *coli/Streptococcus bovis*
- *Streptococcus intermedius*
- *Streptococcus mitis/Streptococcus oralis*
- *Streptococcus mutans*
- *Streptococcus ovis*
- *Streptococcus parasanguinis*
- *Streptococcus pluranimalium*
- *Streptococcus pneumoniae*
- *Streptococcus porcinus*
- *Streptococcus pyogenes*
- *Streptococcus salivarius*
- *Streptococcus sanguinis*

- *Streptococcus sobrinus*
- *Streptococcus suis* I
- *Streptococcus suis* II
- *Streptococcus thermophilus*
- *Streptococcus thoraltensis*
- *Streptococcus uberis*
- *Streptococcus vestibularis*
- *Vagococcus fluvialis*

**Staphylococcus aureus* claim contains only the subspecies *aureus*.

GP Well Contents

Table 2-13: GP Well Contents

Well	Test	Mnemonic	Amount/Well
2	D-AMYGDALIN	AMY	0.1875 mg
4	PHOSPHATIDYLINOSITOL PHOSPHOLIPASE C	PIPLC	0.015 mg
5	D-XYLOSE	dXYL	0.3 mg
8	ARGININE DIHYDROLASE 1	ADH1	0.111 mg
9	BETA-GALACTOSIDASE	BGAL	0.036 mg
11	ALPHA-GLUCOSIDASE	AGLU	0.036 mg
13	Ala-Phe-Pro ARYLAMIDASE	APPA	0.0384 mg
14	CYCLODEXTRIN	CDEX	0.3 mg
15	L-Aspartate ARYLAMIDASE	AspA	0.024 mg
16	BETA GALACTOPYRANOSIDASE	BGAR	0.00204 mg
17	ALPHA-MANNOSIDASE	AMAN	0.036 mg
19	PHOSPHATASE	PHOS	0.0504 mg
20	Leucine ARYLAMIDASE	LeuA	0.0234 mg
23	L-Proline ARYLAMIDASE	ProA	0.0234 mg
24	BETA GLUCURONIDASE	BGURr	0.0018 mg
25	ALPHA-GALACTOSIDASE	AGAL	0.036 mg
26	L-Pyrrolydonyl-ARYLAMIDASE	PyrA	0.018 mg
27	BETA-GLUCURONIDASE	BGUR	0.0378 mg
28	Alanine ARYLAMIDASE	AlaA	0.0216 mg
29	Tyrosine ARYLAMIDASE	TyrA	0.0276 mg
30	D-SORBITOL	dSOR	0.1875 mg
31	UREASE	URE	0.15 mg

Table 2-13: GP Well Contents

Well	Test	Mnemonic	Amount/Well
32	POLYMIXIN B RESISTANCE	POLYB	0.00093 mg
37	D-GALACTOSE	dGAL	0.3 mg
38	D-RIBOSE	dRIB	0.3 mg
39	L-LACTATE alkalinization	lLATk	0.15 mg
42	LACTOSE	LAC	0.96 mg
44	N-ACETYL-D-GLUCOSAMINE	NAG	0.3 mg
45	D-MALTOSE	dMAL	0.3 mg
46	BACITRACIN RESISTANCE	BACI	0.0006 mg
47	NOVOBIOCIN RESISTANCE	NOVO	0.000075 mg
50	GROWTH IN 6.5% NaCl	NC6.5	1.68 mg
52	D-MANNITOL	dMAN	0.1875 mg
53	D-MANNOSE	dMNE	0.3 mg
54	METHYL-B-D-GLUCOPYRANOSIDE	MBdG	0.3 mg
56	PULLULAN	PUL	0.3 mg
57	D-RAFFINOSE	dRAF	0.3 mg
58	O/129 RESISTANCE (comp.vibrio.)	O129R	0.0084 mg
59	SALICIN	SAL	0.3 mg
60	SACCHAROSE/SUCROSE	SAC	0.3 mg
62	D-TREHALOSE	dTRE	0.3 mg
63	ARGININE DIHYDROLASE 2	ADH2s	0.27 mg
64	OPTOCHIN RESISTANCE	OPTO	0.000399 mg

Note: *Other well numbers between 1 and 64 not designated in this table are empty.*

GP Supplemental Tests

Table 2-14: GP Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
A-HEM	ALPHA HEMOLYSIS	Certain species produce incomplete hemolysis resulting in a green zone around colonies on blood-based media.		17,18,19,21
AMD/STARCH GLYCOGENac, lARABINOSE, INULIN, MdG, MdM, PULLULAN, SACCHAROSE, dMALTOSE, dMANNITOL, dMANNOSE, dMELEZIT, dMELIBIOSE, dRAFFINOSE, dRIBOSE, dSORBITOL, dTREHALOSE, dXYLOSE, lRHAMNOSE	Acidification of: AMIDON/STARCH, GLYCOGEN, lARABINOSE, INULIN, METHYL-A-D-GLUCOPYRANOSIDE, METHYL-A-D-MANNOPYRANOSIDE, PULLULAN, SACCHAROSE (SUCROSE), D-MALTOSE, D-MANNITOL D-MANNOSE, D-MELEZITOSE, D-MELIBIOSE, D-RAFFINOSE, D-RIBOSE, D-SORBITOL, D-TREHALOSE, D-XYLOSE, L-RHAMNOSE	Acidification of carbon source observed with pH indicators (e.g., phenol red, bromocresol purple, etc.).	Some tests also appear on the GP card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	2,3,4,6,8,11, 13,14,17,18, 19,21,22,24, 25
ANANE, AIFUC, BGLU, BGURase, BNAG, BNAGA, BdFUC, PAL, Pyrro. Ary.	ALPHA-D-N-ACETYLNEURAMINIDASE, ALPHA-L-FUCOSIDASE, BETA-GLUCOSIDASE, BETA-GLURONIDASE, BETA-N-ACETYL-GLUCOSAMINIDASE, BETA-N-ACETYL-GALACTOSAMINIDASE, BETA-D-FUCOSIDASE, ALKALINE PHOSPHATASE, Pyrrolydonyl ARYLAMIDASE	Presence of respective enzyme cleaves substrate generating detectable leaving group (e.g., p-nitrophenol, methyl umbelliferone, beta-naphthylamide, beta-naphthol, p-nitroaniline, 7-amido-methyl-coumarin, etc.)	Presence of enzyme is indicated by generation of a colored or fluorescent product, or a non-colored product that forms color upon addition of a specific reagent.	5,9,17,18,19, 21,22,24,28
Adherence	Adherence to agar	Sticking of colonies to the agar surface	Characteristic of *Rothia mucilaginosa*	21
AER.GROWTH	AEROBIC GROWTH	Growth in air.		18

Table 2-14: GP Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
Arg.hydr.	ARGININE dihydrolase	Hydrolysis of arginine releases an amine resulting in alkalinization of the medium observed with a pH indicator (e.g., purple color formation in the presence of bromocresol purple).		2,17,18,21
B-HEM	BETA HEMOYSIS	Certain species possess hemolysins that give a transparent zone around colonies on blood-based agars.		17,18,21,27
BILE ESC	BILE ESCULIN	Bile-esculin positive organisms are able to grow in the presence of 40% bile and to hydrolyze esculin.		15,20
BILE SOL	BILE SOLUBILITY	Pneumococcal colonies completely lyse and disappear when exposed to a 10% solution of deoxycholate.	Rapid test for *Streptococcus pneumoniae*	21
CAMP (S.au)	CAMP TEST (*Staph. aureus*)	Synergistic hemolysis of *Listeria moncytogenes* colonies by beta-toxin producing colonies of *Staphylococcus aureus.*		21
CAT	CATALASE	Colony placed on a drop of 3% hydrogen peroxide produces gas bubbles. The bacteria that contain cytochrome enzyme are catalase positive.	Differentiation of *Micrococcaceae* (+) from *Streptococcaceae* (–)	17,18,21
CLINDA.S	Clindamycin susceptible	Zone of inhibition around the clindamycin disk >/= 20mm.	Used to differentiate *Lactococcus lactis* and *Lactococcus garvieae*.	12
DEXTRAN	DEXTRAN ON AGAR SAC	Formation of mucoid colonies from production of dextran on sucrose agar		17

Table 2-14: GP Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
ESCULIN	ESCULIN hydrolysis	Hydrolysis of esculin forms esculetin that produces a black pigment in the presence of iron salts.		3,17,18,21
Gas prod.	Gas production	Production of CO_2 from degradation carbohydrate (e.g., glucose) metabolism		21
HIP	HIPPURATE hydrolysis	Hydrolysis of sodium hippurate releases glycine that produces a blue colored product after addition of ninhydrin.		17,18,21
LitmusMILK	Litmus Milk Medium	Acid production in Litmus Milk.		13
NaCl 6.5%	GROWTH IN 6.5% NaCl	Growth in 6.5% NaCl broth.		13
NO3	NITRATE REDUCTION	Test for the ability to reduce nitrate to nitrite.		17,18
NOVO_R, OPTO_R, VANCO_R	NOVOBIOCIN RESISTANCE, OPTOCHIN_RESISTANCE, VANCOMYCIN_RESISTANCE	Ability of certain species to grow in the presence of specific antibacterial compounds		16,17,18,21
NaCl 7.5%	GROWTH IN 7.5% NACL	Ability of certain species to grow in the presence of a high concentration of NaCl		18
PI/OR/RED	PINK/ORANGE/RED PIGMENT	Ability of certain species to produce pink, orange, or red colonies on non-differential media	Characteristic of *Kocuria rosea*	18,21
SATELLITE	SATELLITE behavior	Appearance of satellite colonies of nutritionally deficient *Streptococcaceae* around colonies of *Staphylococcus epidermidis*	Nutritionally deficient *Streptococcaceae* require nutritional factors supplied by metabolism of colonies of *Staphylococcus epidermidis*.	7,21

Table 2-14: GP Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
Str.sero.A Str.sero.B Str.sero.C Str.sero.D Str.sero.G	Strepto Serology A, Strepto Serology B, Strepto Serology C, Strepto Serology D, Strepto Serology G	Agglutination tests for Streptococcus groups A,B,C,D, and G		1,10,15,17, 18,20,21,22
UREASE	Urease	Hydrolysis of urea releases ammonia resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red)		17,18,21
VP	VOGES PROSKAUER	Ability of some species to produce acetoin from glucose fermentation		17,18,21
YELLOW	YELLOW PIGMENT	Ability of certain species to produce yellow pigmented colonies on non-differential media	For example, used to differentiate *E. casseliflavus* (+) from *E. gallinarum* (-).	17,18,21

Culture Requirements Table

Table 2-15: Culture Requirements

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	Inoculum Density	Manual Dilution for AST	Age of Suspension Before Loading Instrument
GP	TSAB[1] CBA[1] TSA[1] CHOC CHOC PVX CHBA TSAHB CPS-ID3 CNT TSAL MSA BP	12 to 48 hours	35 °C to 37 °C 5% to 10% CO_2 or Aerobic, non CO_2	0.50 to 0.63 McFarland Standard	N/A	≤ 30 minutes
GP and AST GP pair	TSAB[1] CBA[1]	18 to 24 hours	35 °C to 37 °C 5% to 10% CO_2 or Aerobic, non-CO_2	0.50 to 0.63 McFarland Standard	280 µL in 3.0 mL saline	≤ 30 minutes

[1]These media were used in the identification product database development and will give optimal performance.

Culture Requirements Table — Media Abbreviations

BP	=	Baird Parker
CBA	=	Columbia sheep blood agar
CHBA	=	Columbia horse blood agar
CHOC	=	Chocolate agar
CHOC PVX	=	Chocolate Polyvitex
CNT	=	Count-TACT
CPS-ID3	=	CPS-ID3
MSA	=	Mannitol salt agar
TSA	=	Trypticase soy agar
TSAB	=	Trypticase soy agar with 5% sheep blood
TSAHB	=	Trypticase soy agar with 5% horse blood
TSAL	=	TSA with Lecithin and P80

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bioMérieux, Inc.

Use this Product Information with VITEK® 2 Product No. 21342.

bioMérieux, Inc.
Box 15969,
Durham, North Carolina 27704-0969 USA
tel. (1) 800.682.2666

EC REP

bioMérieux sa
au capital de 11 879 045 Euros
673 620 399 RCS LYON
69280 Marcy-l'Etoile/ France
tel. (33) 04 78 87 20 00
fax (33) 04 78 87 20 90
http://www.biomerieux.com

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YST Product Information 3

Intended Use

The VITEK® 2 Yeast identification card (YST) is intended for use with VITEK® 2 systems for the automated identification of most significant yeasts and yeast-like organisms. The VITEK® 2 YST identification card is a single-use disposable. For a list of claimed species, see Organisms Identified by the YST Card, starting on page 3-14.

Description

The YST card is based on established biochemical methods (1,3-6) and newly developed substrates. There are 46 biochemical tests measuring carbon source utilization, nitrogen source utilization, and enzymatic activities. Final results are available in approximately 18 hours.

For a list of well contents, see YST Well Contents on page 3-16.

Precautions

- For In Vitro Diagnostic Use Only.
- Suspensions not within the appropriate zone on the VITEK 2 DENSICHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- The card performs as intended only when used in conjunction with VITEK® 2 systems.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the

tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.

- Ensure that cards are filled properly and do not load any cards that are filled improperly. Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the vacuum fill.
- Give special consideration to specimen source and patient drug or antimicrobic regimen.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in microbial identification testing. Additional testing may be required. See YST Supplemental Tests, on page 3-18.

WARNING

All patient specimens and microbial cultures are potentially infectious and should be treated with universal precautions (8,10).

Storage and Handling

Upon receipt, store VITEK® 2 YST cards unopened in their original package liner at 2 °C to 8 °C.

Specimen Preparation

For specimen preparation, see Culture Requirements Table on page 3-21.

Materials

When used with VITEK® 2 instrumentation, the YST card is a complete system for routine identification testing of most clinically significant yeasts and yeast-like organisms. Required materials are:

- VITEK® 2 YST Card
- VITEK 2 DENSICHEK™
- VITEK 2 DENSICHEK™ Power Adapter
- Lithium Battery for DENSICHEK
- DENSICHEK Calibrator

- VITEK® 2 Cassette
- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- 12 x 75 mm clear plastic (polystyrene) disposable test tubes
- Sterile swabs
- Appropriate agar medium (See Culture Requirements Table on page 3-21.)

Optional accessories:

- Saline dispensers
- Pre-dispensed saline test tubes (saline 0.45% to 0.50%, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Procedure

For product-specific information, see the Culture Requirements Table on page 3-21.

Note: *Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.*

1) Select isolated colonies from a primary plate if culture requirements are met,
or
Subculture organism to be tested to appropriate agar medium and incubate accordingly.

2) Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 mm x 75 mm).

3) Use a sterile swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare the homogenous organism suspension with a density equivalent to a McFarland No. 1.80 to 2.20 using a calibrated VITEK 2 DENSICHEK™.

Note: *Filamentous species may pick up small amounts of glucose from the isolation media. This has the potential for causing false positive reactions. Avoid scraping or rubbing the agar when preparing the organism suspension. For strains which do not readily form a smooth suspension in saline, it is recommended that a wet swab be used to make the suspension.*

Do not rub the agar surface when preparing a suspension using a wet swab.

Note: *Age of suspension must not exceed 30 minutes before inoculating card.*

4) Place the suspension tube and YST card in the cassette.

5) Refer to the User Manuals for the VITEK® 2 Instruments for instructions on data entry and how to load the cassette into the instrument.

6) Follow your local inspecting agency's guidelines for disposal of hazardous waste.

Results

Identification Analytical Techniques

The identification of an organism using the VITEK® 2 systems uses a methodology based on the characteristics of the data and knowledge about the organism and reactions being analyzed. Sufficient data have been collected from known strains to estimate the typical reactions of the claimed species to a set of discriminating biochemicals. If a unique identification pattern is not recognized, a list of possible organisms is given, or the strain is determined to be outside the scope of the database.

The printed lab report contains suggestions for any supplemental tests necessary to complete the identification. If the tests are not sufficient to complete the identification, then standard microbiology references and literature should be consulted.

Certain species may belong to a slashline (mixed) taxa identification. This occurs when the biopattern is the same for the taxa listed. Supplemental tests may be used to separate slashline taxa. The following species belong to the slashline.

Table 3-1: Slashline (mixed) Taxa Identification

Slashline Name	Species Belonging to the Slashline
Candida krusei/C. inconspicua/C. lambica	*Candida krusei* *Candida inconspicua* *Candida lambica*
Kloeckera spp.	*Kloeckera apiculata* *Kloeckera apis* *Kloeckera japonica*

Table 3-1: Slashline (mixed) Taxa Identification

*Rhodotorula glutinis/mucilaginosa/ (Crypto. laurentii)**	*Rhodotorula glutinis* *Rhodotorula mucilaginosa*

*This is also a pseudoslashline.

Certain species may belong to a pseudoslashline (mixed) taxa identification. A pseudoslashline indicates a rare isolate or rare occurrence of the same biopattern. Supplemental tests may be used to separate pseudoslashline taxa. The following species belong to the pseudoslashline taxa.

Table 3-2: Pseudoslashline Taxa

Pseudoslashline name	Species Belonging to Pseudoslashline
Candida sake/(C. famata/ C. lipolytica)	*Candida famata* *Candida lipolytica*
*Rhodotorula glutinis/ mucilaginosa/(Crypto. laurentii)**	*Cryptococcus laurentii*

*This is also a slashline.

Identification Card Qualifying Messages

Table 3-3: Identification Card Qualifying Messages

ID Message Confidence Level	Choices	% Probability	Comments
Excellent	1	96 to 99	
Very Good	1	93 to 95	
Good	1	89 to 92	
Acceptable	1	85 to 88	
Low Discrimination	2 to 3	Sum of choices = 100; after resolution to one choice, percent probability reflects the number associated with selected choice.	2 to 3 taxa exhibit same biopattern. Separate by supplemental testing. Must resolve to mate with susceptibility card.
Unidentified Organism or 0	> 3	n/a	Either > 3 taxa exhibit same biopattern or Very atypical biopattern. Does not correspond to any taxon in the database. Check Gram stain and purity.

Percent Probability

As part of the identification process, the software compares the test set of reactions to the expected set of reactions of each organism, or organism group, that can be identified by the product. A quantitative value, the percent probability, is calculated and relates to how well the observed reactions compare to the typical reactions of each organism. A perfect match between the test reaction pattern and the unique reaction pattern of a single organism, or organism group, would provide a percent probability of 99. When a perfect match is not obtained, it is still possible for the reaction pattern to be sufficiently close to that of an expected reaction pattern such that a clear decision can be provided about the organism identification. The range of percent probabilities in the one-choice case is 85 to 99. Values closer to 99 indicate a closer match to the typical pattern for the given organism.

When the reaction pattern is not sufficient to discriminate between two to three organisms, the percent probabilities reflect this ambiguity. The reported probability values indicate, relatively, the order in which the reaction pattern best corresponds to the listed possibilities. The order does not, however, suggest that the pattern match to one of the possible identifications is clearly superior to another. The probability characteristic of an overall sum of 100 is retained through the calculation process. After resolution to one choice, the probability characteristic of the single choice is retained.

Note: *(VITEK® 2 only) Results appear as **+**, **–**, or **?**. The **?** indicates a reaction too close to the threshold to be considered a clear positive or negative reaction.*

Note: *(VITEK® 2 Compact only) Results appear as **+**, **–**, (–) or (+). When a clear positive or a clear negative cannot be determined, the result may appear as a weak negative (–) which indicates a reaction slightly below the threshold or a weak positive (+) which indicates a reaction slightly above the threshold.*

Additional Information on Lab Report

Supplemental test—External test that allows the user to resolve a slashline or Low Discrimination identification.

Contraindicating test—Test result that is unusual for a reported taxon.

Notes Associated with Certain Taxa

Table 3-4: Notes Associated with Certain Taxa

Note	Taxa
Possibility of *Cryptococcus albidus*	*Rhodotorula glutinis/mucilaginosa (Cryptococcus laurentii)*
Possibility of *Geotrichum candidum*	*Geotrichum klebahnii*
Highly pathogenic organism	*Cryptococcus neoformans*

Notes Associated with an Improperly Filled Card or with a Negative Profile (biopattern)

- For the case where the instrument determines that the card has not been filled:
  "Terminated card—no organism suspension detected."
- For the case where the time between two readings is higher than 40 minutes:
  "CARD ERROR—Missing data."
- For the case where there is a negative profile:
  "Organism with low reactivity biopattern—please check viability."
- When a biopattern is calculated for an unknown organism that is completely negative or consists of both negative tests and tests that fall within the uncertainty zone, the identification call will be "Nonreactive biopattern."

The following species could potentially trigger this note if a test was atypical or fell within the uncertainty zone:

Table 3-5: Non-Reactive Species

Candida sake
Candida zeylanoides
Malassezia furfur
Malassezia pachydermatis
Zygosaccharomyces bailii

Quality Control

Quality control organisms and their expected results are listed in the VITEK® 2 YST Quality Control Table and should be processed according to the procedure for test isolates outlined in this document. The YST card will identify the quality control organisms as one-choice, or within a low discrimination, or slashline identification. See the Quality Control Section for more details.

Frequency of Testing

Currently, it is recommended that you use your most stringent inspecting agency's guidelines for frequency of identification product testing.

Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Product Information results.

If the results do not meet the criteria, subculture for purity and repeat test. If discrepant results are repeated, perform an alternate identification method.

Note: *The recommended and supplemental QC strains do not exhibit a negative reaction for two tests, LeuA and dGLU. These tests serve as a positive control for most taxa claimed by the YST card. Reproducible negative reactions are only observed with strains of Malassezia spp. Malassezia was not included for QC, since cultures of this genus are difficult to maintain.*

Testing and Storage of QC Organisms

- Rehydrate organism according to the manufacturer's instructions.
- Streak organism to SDA.
- Incubate for 18 to 24 hours.
- All QC Organisms are incubated at 35 °C to 37 °C except *Prototheca wickerhamii* ATCC® 16529, which is incubated at 28 °C to 30 °C.
- Check for purity. Perform second subculture for testing.
- Streak organism to SDA.
- Incubate for 18 to 24 hours.

Storage Conditions

Short-Term Storage

1) Streak to a SDA plate or slant.

2) Incubate for 24 hours at the appropriate temperature.

3) Refrigerate at 2 °C to 8 °C for up to two weeks.

4) Subculture once as described above and use for QC.

Long-Term Storage

1) Make a heavy suspension in Tryptic Soy Broth with 15% glycerol.

2) Freeze at –70 °C.

3) Subculture to SDA twice before running QC.

Note: *Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.*

YST Quality Control Table

***Candida glabrata* ATCC® MYA-2950**
***Candida lusitaniae* ATCC 34449**
***Candida utilis* ATCC 9950**
***Geotrichum capitatum* ATCC 28576**
***Kloeckera apis* ATCC 32857**
***Prototheca wickerhamii* ATCC 16529**
***Trichosporon mucoides* ATCC 204094**

The organisms below marked with an asterisk indicate additional quality control if required by local regulatory agencies.

Table 3-6: *QC Organism: *Candida glabrata* ATCC MYA-2950

LysA	–	ARBa	–	**GGT**	–	lRHAa	–	**NO3a**	–	CITa	–
lMLTa	–	AMYa	–	**dMALa**	–	XLTa	v	**lARAa**	–	GRTas	–
LeuA	+	dGALa	–	**dRAFa**	–	dSORa	–	**dGATa**	–	lPROa	v
ARG	v	GENa	–	**NAGA1**	v	SACa	–	**ESC**	–	2KGa	–
ERYa	–	dGLUa	+	**dMNEa**	+	URE	–	**lGLTA**	v	NAGa	–
GLYLa	–	LACa	–	**dMELa**	–	AGLU	–	**dXYLa**	–	dGNTa	v
TyrA	–	MAdGa	–	**dMLZa**	–	dTURa	–	**LATa**	–		
BNAG	–	dCELa	–	**ISBEa**	–	dTREa	+	**ACEa**	v		

+ = 95% to100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 3-7: *QC Organism: *Candida lusitaniae* ATCC 34449

LysA	–	ARBa	+	**GGT**	v	lRHAa	v	**NO3a**	–	CITa	+
lMLTa	+	AMYa	+	**dMALa**	v	XLTa	v	**lARAa**	–	GRTas	v
LeuA	+	dGALa	v	**dRAFa**	–	dSORa	+	**dGATa**	v	lPROa	+
ARG	v	GENa	v	**NAGA1**	v	SACa	+	**ESC**	+	2KGa	+
ERYa	–	dGLUa	+	**dMNEa**	+	URE	–	**lGLTA**	+	NAGa	+
GLYLa	v	LACa	–	**dMELa**	–	AGLU	v	**dXYLa**	v	dGNTa	v
TyrA	v	MAdGa	v	**dMLZa**	v	dTURa	+	**LATa**	v		
BNAG	–	dCELa	+	**ISBEa**	+	dTREa	v	**ACEa**	+		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 3-8: *QC Organism: *Candida utilis* ATCC 9950

LysA	–	ARBa	v	**GGT**	v	lRHAa	–	**NO3a**	+	CITa	v
lMLTa	v	AMYa	v	**dMALa**	v	XLTa	v	**lARAa**	–	GRTas	v
LeuA	+	dGALa	v	**dRAFa**	+	dSORa	v	**dGATa**	v	lPROa	v
ARG	v	GENa	v	**NAGA1**	v	SACa	+	**ESC**	v	2KGa	v
ERYa	–	dGLUa	+	**dMNEa**	+	URE	v	**lGLTA**	v	NAGa	v
GLYLa	+	LACa	–	**dMELa**	–	AGLU	v	**dXYLa**	v	dGNTa	v
TyrA	v	MAdGa	v	**dMLZa**	+	dTURa	v	**LATa**	v		
BNAG	–	dCELa	v	**lSBEa**	–	dTREa	v	**ACEa**	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 3-9: *QC Organism: *Geotrichum capitatum* ATCC 28576

LysA	+	ARBa	–	**GGT**	v	lRHAa	–	**NO3a**	–	CITa	–
lMLTa	v	AMYa	–	**dMALa**	–	XLTa	–	**lARAa**	–	GRTas	v
LeuA	+	dGALa	v	**dRAFa**	–	dSORa	–	**dGATa**	v	lPROa	v
ARG	v	GENa	–	**NAGA1**	–	SACa	–	**ESC**	–	2KGa	v
ERYa	–	dGLUa	+	**dMNEa**	v	URE	v	**lGLTA**	v	NAGa	v
GLYLa	v	LACa	–	**dMELa**	–	AGLU	–	**dXYLa**	–	dGNTa	v
TyrA	+	MAdGa	v	**dMLZa**	–	dTURa	–	**LATa**	v		
BNAG	–	dCELa	–	**lSBEa**	v	dTREa	–	**ACEa**	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 3-10: *QC Organism: *Kloeckera apis* ATCC 32857

LysA	v	ARBa	v	**GGT**	v	lRHAa	–	**NO3a**	–	CITa	–
lMLTa	–	AMYa	v	**dMALa**	v	XLTa	v	**lARAa**	–	GRTas	–
LeuA	+	dGALa	–	**dRAFa**	–	dSORa	–	**dGATa**	–	lPROa	–
ARG	–	GENa	+	**NAGA1**	–	SACa	–	**ESC**	v	2KGa	v
ERYa	–	dGLUa	+	**dMNEa**	+	URE	–	**lGLTA**	–	NAGa	–
GLYLa	–	LACa	–	**dMELa**	–	AGLU	–	**dXYLa**	–	dGNTa	–
TyrA	v	MAdGa	v	**dMLZa**	–	dTURa	–	**LATa**	–		
BNAG	–	dCELa	v	**lSBEa**	–	dTREa	–	**ACEa**	v		

+ = 95% to 100% positive; v = 6% to -94% positive; – = 0% to 5% positive

Table 3-11: *QC Organism: *Prototheca wickerhamii* ATCC 16529

LysA	–	ARBa	–	**GGT**	–	lRHAa	–	**NO3a**	–	CITa	–
lMLTa	–	AMYa	–	**dMALa**	v	XLTa	v	**lARAa**	–	GRTas	v
LeuA	+	dGALa	v	**dRAFa**	–	dSORa	–	**dGATa**	v	lPROa	v
ARG	v	GENa	–	**NAGA1**	–	SACa	–	**ESC**	–	2KGa	v
ERYa	–	dGLUa	+	**dMNEa**	v	URE	v	**lGLTA**	v	NAGa	v
GLYLa	v	LACa	–	**dMELa**	–	AGLU	–	**dXYLa**	v	dGNTa	v
TyrA	–	MAdGa	–	**dMLZa**	–	dTURa	–	**LATa**	v		
BNAG	–	dCELa	–	**lSBEa**	–	dTREa	+	**ACEa**	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Table 3-12: Recommended QC Organism: *Trichosporon mucoides* ATCC 204094

LysA	v	ARBa	v	**GGT**	+	lRHAa	+	**NO3a**	v	CITa	v
lMLTa	v	AMYa	–	**dMALa**	+	XLTa	+	**lARAa**	+	GRTas	+
LeuA	+	dGALa	+	**dRAFa**	+	dSORa	v	**dGATa**	+	lPROa	v
ARG	+	GENa	v	**NAGA1**	v	SACa	v	**ESC**	v	2KGa	+
ERYa	+	dGLUa	+	**dMNEa**	v	URE	+	**lGLTA**	v	NAGa	v
GLYLa	–	LACa	+	**dMELa**	+	AGLU	+	**dXYLa**	+	dGNTa	+
TyrA	v	MAdGa	+	**dMLZa**	v	dTURa	v	**LATa**	+		
BNAG	+	dCELa	v	**lSBEa**	v	dTREa	v	**ACEa**	v		

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive

Limitations

The VITEK® 2 YST card cannot be used with direct clinical samples or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

Newly described or rare species may not be included in the YST database. Selected species will be added as strains become available. Testing of unclaimed species may result in an unidentified result or a misidentification.

Performance Characteristics

In a recent multi-site clinical study*, the performance of the VITEK® 2 YST was evaluated using 623 clinical and stock isolates of both commonly and rarely observed species of yeast and yeast-like organisms. The reference identification was determined with api® 20C AUX identification kits. Overall, the VITEK® 2 YST correctly identified 98.6% of the isolates, including 11.5% low discrimination with the correct species listed. Misidentifications occurred at 0.9% and no identifications occurred at 0.5%.

Organisms Identified by the YST Card

- *Candida albicans*
- *Candida boidinii*
- *Candida catenulata*
- *Candida colliculosa*
- *Candida dubliniensis*
- *Candida famata*
- *Candida freyschussii*
- *Candida glabrata*
- *Candida guilliermondii*
- *Candida haemulonii*
- *Candida intermedia*
- *Candida kefyr*
- *Candida krusei/Candida inconspicua/Candida lambica*
- *Candida lipolytica*
- *Candida lusitaniae*
- *Candida magnoliae*
- *Candida norvegensis*

* Data on file at bioMérieux, Inc.

- *Candida parapsilosis*
- *Candida pelliculosa*
- *Candida pulcherrima*
- *Candida rugosa*
- *Candida sake*
- *Candida sphaerica*
- *Candida tropicalis*
- *Candida utilis*
- *Candida zeylanoides*
- *Cryptococcus albidus*
- *Cryptococcus laurentii*
- *Cryptococcus neoformans*
- *Cryptococcus terreus*
- *Cryptococcus uniguttulatus*
- *Geotrichum capitatum*
- *Geotrichum klebahnii*
- *Kloeckera* spp.
- *Kodamaea ohmeri*
- *Malassezia furfur*
- *Malassezia pachydermatis*
- *Pichia farinosa*
- *Prototheca wickerhamii*
- *Prototheca zopfii*
- *Rhodotorula glutinis/Rhodotorula mucilaginosa*
- *Rhodotorula minuta*
- *Saccharomyces cerevisiae*
- *Sporobolomyces salmonicolor*
- *Stephanoascus ciferrii*
- *Trichosporon asahii*
- *Trichosporon inkin*
- *Trichosporon mucoides*
- *Zygosaccharomyces bailii*

YST Well Contents

Table 3-13: YST Well Contents

Well	Test	Mnemonic	Amount/Well
3	L-Lysine-ARYLAMIDASE	LysA	0.0228 mg
4	L-MALATE assimilation	lMLTa	0.15 mg
5	Leucine-ARYLAMIDASE	LeuA	0.0234 mg
7	ARGININE GP	ARG	0.15 mg
10	ERYTHRITOL assimilation	ERYa	0.3 mg
12	GLYCEROL assimilation	GLYLa	0.16 µL
13	Tyrosine ARYLAMIDASE	TyrA	0.0276 mg
14	BETA-N-ACETYL-GLUCOSAMINIDASE	BNAG	0.0408 mg
15	ARBUTINE assimilation	ARBa	0.3 mg
18	AMYGDALINE assimilation	AMYa	0.3 mg
19	D-GALACTOSE assimilation	dGALa	0.3 mg
20	GENTIOBIOSE assimilation	GENa	0.3 mg
21	D-GLUCOSE assimilation	dGLUa	0.3 mg
23	LACTOSE assimilation	LACa	0.96 mg
24	METHYL-A-D-GLUCOPYRANOSIDE assimilation	MAdGa	0.3 mg
26	D-CELLOBIOSE assimilation	dCELa	0.3 mg
27	GAMMA-GLUTAMYL-TRANSFERASE	GGT	0.0228 mg
28	D-MALTOSE assimilation	dMALa	0.3 mg
29	D-RAFFINOSE assimilation	dRAFa	0.3 mg
30	PNP-N-acetyl-BD-galactosaminidase 1	NAGA1	0.0306 mg
32	D-MANNOSE assimilation	dMNEa	0.3 mg
33	D-MELIBIOSE assimilation	dMELa	0.3 mg
34	D-MELEZITOSE assimilation	dMLZa	0.3 mg
38	L-SORBOSE assimilation	lSBEa	0.3 mg
39	L-RHAMNOSE assimilation	lRHAa	0.3 mg
40	XYLITOL assimilation	XLTa	0.3 mg
42	D-SORBITOL assimilation	dSORa	0.1875 mg
44	SACCHAROSE/SUCROSE assimilation	SACa	0.3 mg
45	UREASE	URE	0.15 mg
46	ALPHA-GLUCOSIDASE	AGLU	0.036 mg

Table 3-13: YST Well Contents

Well	Test	Mnemonic	Amount/Well
47	D-TURANOSE assimilation	dTURa	0.3 mg
48	D-TREHALOSE assimilation	dTREa	0.3 mg
49	NITRATE assimilation	NO3a	0.03 mg
51	L-ARABINOSE assimilation	lARAa	0.3 mg
52	D-GALACTURONATE assimilation	dGATa	0.15 mg
53	ESCULIN hydrolyse	ESC	0.225 mg
54	L-GLUTAMATE assimilation	lGLTa	0.15 mg
55	D-XYLOSE assimilation	dXYLa	0.3 mg
56	DL-LACTATE assimilation	LATa	0.15 mg
58	ACETATE assimilation	ACEa	0.15 mg
59	CITRATE (SODIUM) assimilation	CITa	0.15 mg
60	GLUCURONATE ASSIMILATION	GRTas	0.15 mg
61	L-PROLINE assimilation	lPROa	0.15 mg
62	2-KETO-D-GLUCONATE assimilation	2KGa	0.15 mg
63	N-ACETYL-GLUCOSAMINE assimilation	NAGa	0.15 mg
64	D-GLUCONATE assimilation	dGNTa	0.15 mg

Note: *Other well numbers between 1 and 64 not designated in this table are empty.*

YST Supplemental Tests

Table 3-14: YST Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
2KG	2-KETO-D-GLUCONATE	Ability to use 2-keto-D-gluconate as a sole carbon source.		2,3,5
4ASCOSPOR.	4 Ascospores	Microscopic examination for the presence of four ascospores per ascus.		2,3,5
Apic.CELLS	APICULATE CELLS	Microscopic examination for the presence of apiculate (lemon-drop shaped) cells.		2,3,5
Arthro.	Arthroconidia	Microscopic examination for the presence of arthroconidia (fragmentation of hyphae into rectangular cells) on morphology agar (e.g., cornmeal agar).		2,3,5
CAROTENOID	CAROTENOID PIGMENT	Presence of red, pink, or orange pigment on Sabouraud Dextrose agar.		2,3,5
dCELLOB.a	D-CELLOBIOSE Assimilation	Ability to use cellobiose as the sole carbon source.		2,3,5
CHLS	Chlamydospores	Microscopic examination for the presence of chlamydospores on morphology agar (e.g., cornmeal agar).		2,3,5
DULCITOLa	DULCITOL Assimilation	Ability to use dulcitol (galactitol) as the sole carbon source.		2,3,5
ERYTHRIT.a	ERYTHRITOL Assimilation	Ability to use erythritol as the sole carbon source.		2,3,5
dGALACT.a	D-GALACTOSE Assimilation	Ability to use galactose as the sole carbon source.		2,3,5
dGALf	D-GALACTOSE Fermentation	Production of gas from fermentation of galactose.		2,3,5
dGLUf	D-GLUCOSE Fermentation	Production of gas from fermentation of glucose.		2,3,5

Table 3-14: YST Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
w/o OIL	GROWTH WITHOUT OIL	Ability to grow on Sabouraud Dextrose agar without the addition of a fatty acid source (e.g., olive oil).		2,3,5
HYPH/PH	HYPHAE/ PSEUDOHYHPAE	Microscopic examination for the presence of filaments on morphology agar (e.g., cornmeal agar).		2,3,5
INOSITOLa	myo-INOSITOL Assimilation	Ability to use inositol as the sole carbon source.		2,3,5
NITRATEa	NITRATE Assimilation	Ability to use potassium nitrate as the sole nitrogen source.		2,3,5,9
LACTOSEa	LACTOSE Assimilation	Ability to use lactose as the sole carbon source.		2,3,5
lARABIN.a	L-ARABINOSE Assimilation	Ability to use arabinose as the sole carbon source.		2,3,5
dMALTOSEa	D-MALTOSE Assimilation	Ability to use maltose as the sole carbon source.		2,3,5
dMALf	D-MALTOSE Fermentation	Production of gas from fermentation of maltose.		2,3,5
dMELIBIO.a	D-MELIBIOSE Assimilation	Ability to use melibiose as the sole carbon source.		2,3,5
OX_Phe	Phenol Oxidase	Ability to produce brown to black pigment from phenol oxidase activity on phenolic substrates (e.g., caffeic acid or birdseed agar).		7
dRAFFIN.a	D-RAFFINOSE Assimilation	Ability to use raffinose as the sole carbon source.		2,3,5
lRHAMNOSEa	L-RHAMNOSE Assimilation	Ability to use rhamnose as the sole carbon source.		2,3,5
SACCHAR.a	SACCHAROSE/ SUCROSE Assimilation	Ability to use sucrose as the sole carbon source.		2,3,5
SACf	SACCAROSE/ SUCROSE Fermentation	Production of gas from fermentation of sucrose.		2,3,5
SATELLITE	SATELLITE behavior	Formation of satellite colonies on Sabouraud Dextrose agar.		2,3,5

Table 3-14: YST Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
Sphe.CELLS	Spherical CELLS	Microscopic examination for the presence of spherical cells.	*Candida famata* can be differentiated from *Candida guilliermondii* by the shape of the cells. *Candida famata* has mostly spherical cells while *Candida guilliermondii* has mostly ovoid cells.	2,3,5
SPORANGE	SPORANGE	Microscopic examination for the presence of sporangia.		6
dTREHAL.a	D-TREHALOSE Assimilation	Ability to use trehalose as the sole carbon source.		2,3,5
dTREf	D-TREHALOSE Fermentation	Production of gas from fermentation of trehalose.		2,3,5
UREASE	Urease	Hydrolysis of urea releases ammonia resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).		2,3,5
dXYLOSEa	D-XYLOSE Assimilation	Ability to use xylose as the sole carbon source.		2,3,5

Culture Requirements Table

Table 3-15: Culture Requirements

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	Inoculum Density	Manual Dilution for AST	Age of Suspension Before Loading Instrument
YST	SDA[1] TSAB[1] CBA IMA TSA CHBA CPS-ID3	18 to 72 hours	30 °C to 37 °C aerobic, non-CO_2 (or 25 °C to 30 °C for species that do not tolerate 30 °C to 37 °C)	1.80 to 2.20 McFarland Standard	N/A	≤ 30 minutes
YST and AST-YST Pair	SDA[1] TSAB[1] CBA TSA CHBA CPS-ID3	18 to 72 hours	35 °C to 37 °C aerobic, non-CO_2	1.80 to 2.20 McFarland Standard	280µL in 3.0 mL saline	≤ 30 minutes

[1]These media were used in the identification product database development and will give optimal performance

Culture Requirements Table — Media Abbreviations

CBA	=	Columbia sheep blood agar
CHBA	=	Columbia Horse blood agar
CPS ID3	=	CPS ID3 Agar
IMA	=	Inhibitory mould agar
SDA	=	Sabouraud dextrose agar
TSA	=	Trypticase soy agar
TSAB	=	Trypticase soy agar with sheep blood

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bioMérieux, Inc.

Use this Product Information with VITEK® 2 Product No. 21343.

bioMérieux, Inc.
Box 15969,
Durham, North Carolina 27704-0969 USA
tel. (1) 800.682.2666

EC REP

bioMérieux sa
au capital de 11 879 045 Euros
673 620 399 RCS LYON
69280 Marcy-l'Etoile/ France
tel. (33) 04 78 87 20 00
fax (33) 04 78 87 20 90
http://www.biomerieux.com

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NH Product Information 4

Intended Use

The VITEK® 2 Neisseria-Haemophilus Identification Card (NH) is intended for use with the VITEK® 2 Systems for the automated identification of most clinically significant fastidious organisms. The VITEK® 2 NH identification card is a single-use disposable. For a list of claimed species, see Organisms Identified by the NH Card, starting on page 4-13.

Description

The NH Card is based on established biochemical methods and newly developed substrates measuring carbon source utilization and enzymatic activities. There are 30 biochemical tests. Final identification results are available in approximately six hours.

For a list of well contents, see NH Well Contents, starting on page 4-15.

Precautions

- For In Vitro Diagnostic Use Only.
- Suspensions not within the appropriate zone on the VITEK 2 DENSICHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.
- The card performs as intended only when used in conjunction with VITEK® 2 Systems.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the

tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.

- Ensure that cards are filled properly and do not load any cards that are filled improperly. Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the vacuum fill.
- Give special consideration to specimen source and patient drug or antimicrobic regimen.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in microbial identification testing. Additional testing may be required (NH Supplemental Tests on page 4-17).

WARNING

All patient specimens and microbial cultures are potentially infectious and should be treated with universal precautions (11, 12).

Storage and Handling

Upon receipt, VITEK® 2 NH Cards must be stored unopened in their original package liner at 2 °C to 8 °C.

Specimen Preparation

For specimen preparation information, see the Culture Requirements on page 4-20.

Materials

When used with VITEK® 2 instrumentation, the NH Card is a complete system for routine identification testing of most significant fastidious organisms. Required materials are:

- VITEK® 2 NH Card
- VITEK 2 DENSICHEK™
- VITEK 2 DENSICHEK™ Power Adapter
- Lithium Battery for DENSICHEK
- DENSICHEK Calibrator
- VITEK® 2 Cassette
- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- 12 x 75 mm clear plastic (polystyrene) disposable test tubes
- Sterile sticks or swabs
- Appropriate agar medium (See Culture Requirements on page 4-20)

Optional accessories:

- Saline dispensers
- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Procedure

For product-specific information, see Culture Requirements on page 4-20.

Note: *The inoculum must be prepared from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.*

1) Select isolated colonies from a primary plate if culture requirements are met,

or

Subculture the organism to be tested to an appropriate agar medium and incubate accordingly (see Table 4-15).

2) Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.5% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 x 75 mm).

3) Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare the homogenous organism suspension with a density equivalent to McFarland No. 2.70 to 3.30 using the calibrated VITEK 2 DENSICHEK™.

Note: *Age of suspension must not exceed 30 minutes before inoculating card.*

4) Place the suspension tube and NH card in the cassette.

5) Refer to the Instrument User Manual for instructions on data entry and how to load the cassette into the instrument.

6) Follow your local inspecting agency's guidelines for disposal of hazardous waste.

Results

Identification Analytical Techniques

The identification of an organism using the VITEK® 2 Systems uses a methodology based on the characteristics of the data and knowledge about the organism and reactions being analyzed. Sufficient data have been collected from known strains to estimate the typical reactions of the claimed species to a set of discriminating biochemicals. If a unique identification pattern is not recognized, a list of possible organisms is given, or the strain is determined to be outside the scope of the database.

The printed lab report contains suggestions for any supplemental tests necessary to complete the identification. If the tests are not sufficient to complete the identification, then standard microbiology references and literature should be consulted.

Certain species may belong to a slashline (mixed) taxa identification. This occurs when the biopattern is the same for the taxa listed. Supplemental tests may be used to separate slashline taxa. The following species belong to NH slashline taxa.

Table 4-1: NH Slashline Taxa

Slashline Name	Species Belonging to the Slashline
Haemophilus aphrophilus/paraphrophilus	*Haemophilus aphrophilus* *Haemophilus paraphrophilus*

Identification Card Qualifying Messages

Table 4-2: Identification Card Qualifying Messages

ID Message Confidence Level	Choices	% Probability	Comments
Excellent	1	96 to 99	
Very Good	1	93 to 95	
Good	1	89 to 92	
Acceptable	1	85 to 88	
Low Discrimination	2 to 3	Sum of choices = 100; after resolution to one choice, percent probability reflects the number associated with selected choice.	2 to 3 taxa exhibit same biopattern. Separate by supplemental testing.
Unidentified Organism	> 3 or 0	n/a	Either > 3 taxa exhibit same biopattern. or Very atypical biopattern. Does not correspond to any taxon in the database. Check Gram stain and purity.

Percent Probability

As part of the identification process, the software compares the test set of reactions to the expected set of reactions of each organism, or organism group, that can be identified by the product. A quantitative value, the percent probability, is calculated and relates to how well the observed reactions compare to the typical reactions of each organism. A perfect match between the test reaction pattern and the unique reaction pattern of a single organism, or organism group, would provide a percent probability of 99. When a perfect match is not obtained, it is still possible for the reaction pattern to be sufficiently close to that of an expected reaction pattern such that a clear decision can be provided about the organism identification. The range of percent probabilities in the one-choice case is 85 to 99. Values closer to 99 indicate a closer match to the typical pattern for the given organism.

When the reaction pattern is not sufficient to discriminate between two to three organisms, the percent probabilities reflect this ambiguity. The reported probability values indicate, relatively, the order in which the reaction pattern best corresponds to the listed possibilities. The order does not, however, suggest that the pattern match to one of the possible identifications is clearly superior to another. The probability characteristic of an overall sum of 100 is retained through the calculation process. After resolution to one choice, the probability characteristic of the single choice is retained.

Note: *(VITEK® 2 only) Results appear as +, –, or **?**. The **?** indicates a reaction too close to the threshold to be considered a clear positive or negative reaction.*

Note: *(VITEK® 2 Compact only) Results appear as +, –, (–) or (+). When a clear positive or a clear negative cannot be determined, the result may appear as a weak negative (–), which indicates a reaction slightly below the threshold, or a weak positive (+), which indicates a reaction slightly above the threshold.*

Additional Information on Lab Report

Supplemental test — External test that allows the user to resolve a slashline or Low Discrimination identification.

Contraindicating test — Test result that is unusual for a reported taxon.

Notes Associated with Certain Taxa

Table 4-3: Notes Associated with Certain Taxa

Taxa	Note
Haemophilus influenzae	*Haemophilus aegyptius* is a recognized species but there is controversy as to whether it should be retained as a legitimate species. *Haemophilus aegyptius* is indistinguishable from *H. influenzae* by either DNA/DNA hybridization or by any single phenotypic test. Isolates of *H. aegyptius* exhibit distinct pathogenicity and are associated with cases of acute purulent conjunctivitis. *Haemophilus influenzae* biogroup *Aegyptius* is also indistinguishable from *H. aegyptius* and *H. influenzae*, but is considered the etiologic agent of Brazilian purpuric fever, which is a systemic pediatric infection that is typically preceded by purulent conjunctivitis that resolves before the onset of the systemic infection. Consequently, isolates of *H. aegyptius, H. influenzae* biogroup *Aegyptius*, and other biogroups of *H. influenzae* will all identify as *H. influenzae* when tested with the NH card.
Neisseria meningitidis	Highly pathogenic organism.

Notes Associated with Improperly Filled Card or Negative Profile (biopattern)

- For the case where the instrument determines that the card has not been filled:
  "Terminated card — no organism suspension detected."
- For the case where the time between two readings is higher than 40 minutes:
  "CARD ERROR — Missing data."
- For the case where there is a negative profile:
  "Organism with low reactivity biopattern — please check viability."
- When a biopattern is calculated for an unknown organism that is completely negative or consists of both negative tests and tests that fall within the uncertainty zone, the identification call will be:
  "Nonreactive biopattern."

The following species could potentially trigger this note if a test was atypical or fell within the uncertainty zone.

Table 4-4: Non-Reactive Species

Campylobacter jejuni ssp. *jejuni*

Quality Control

Quality control organisms and their expected results are located in the VITEK® 2 NH Quality Control Tables. Process these according to the procedure for test isolates outlined in this document. The NH card identifies the quality control organisms as one-choice, or within a low discrimination, or slashline identification. See NH Quality Control Tables for more details.

Frequency of Testing

Currently, it is recommended that you use your most stringent inspecting agency's guidelines for frequency of identification product testing.

Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Product Information results.

If the results do not meet the criteria, subculture for purity and repeat the test. If discrepant results are repeated, perform an alternate identification method.

Testing and Storage of QC Organisms

- Rehydrate organism per the manufacturer's instructions.
- Fastidious: Use Chocolate agar and incubate at 35 °C to 37 °C in 5% to10% CO_2. Incubate for 18 to 24 hours or until sufficient growth is obtained.
- Campylobacter: Use Trypticase Soy with 5% sheep blood agar and incubate 35 °C to 37 °C in microaerophilic conditions for 18 to 24 hours or until sufficient growth is obtained.
- Check for purity. Perform second subculture for testing.

Storage Conditions

Short-Term Storage

Short-term storage is not recommended. Cultures maintained by other methods, specifically those maintained on agar plates or slants for long periods of time at room temperature or at 2–8 °C, are subject to loss or change of important biochemical characteristics.

Long-Term Storage

1) Make a heavy suspension in Tryptic Soy Broth (TSB) with 15% glycerol.

2) Freeze at –70 °C.

3) Subculture twice before running QC.

Note: *Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.*

NH Quality Control Tables

***Campylobacter jejuni* ssp. *jejuni* ATCC® BAA-1153**
***Eikenella corrodens* ATCC BAA-1152**
***Gardnerella vaginalis* ATCC BAA-1154**
***Haemophilus aphrophilus* ATCC 33389**
***Haemophilus influenzae* ATCC 9007**
***Neisseria gonorrhoeae* ATCC 19424**
***Neisseria lactamica* ATCC 23970**
***Oligella urethralis* ATCC 17960**

The organisms below marked with an asterisk indicate additional quality control if required by local regulatory agencies.

Table 4-5: *QC Organism: *Campylobacter jejuni* ssp. *jejuni* ATCC BAA-1153

ArgA	**–**	PheA	v	**GLYG**	**–**	BGALi	–	**MTE**	**–**
GGT	**v**	ProA	–	**dMNE**	**–**	ODC	v	**IGLM**	**v**
LysA	–	PryA	+	**dMAL**	**–**	AARA	–	**PHOS**	–
dGAL	**–**	TyrA	**–**	**SAC**	**–**	PVATE	v	**dRIB2**	**–**
LeuA	**+**	APPA	**–**	**NAG**	**–**	PHC	**–**	**OPS**	**v**
ELLM	**v**	dGLU	**–**	**URE**	**–**	dMLT	v	**dXYL**	**–**

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Table 4-6: *QC Organism: *Eikenella corrodens* ATCC BAA-1152

ArgA	**–**	PheA	**–**	**GLYG**	**–**	BGALi	**–**	**MTE**	**–**
GGT	**–**	ProA	**+**	**dMNE**	**–**	ODC	+	**IGLM**	**v**
LysA	**–**	PryA	**–**	**dMAL**	**–**	AARA	**–**	**PHOS**	**–**
dGAL	**–**	TyrA	**–**	**SAC**	**–**	PVATE	**–**	**dRIB2**	**–**
LeuA	**+**	APPA	**+**	**NAG**	**–**	PHC	**–**	**OPS**	**–**
ELLM	**+**	dGLU	**–**	**URE**	**–**	dMLT	**v**	**dXYL**	**–**

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Table 4-7: *QC Organism: *Gardnerella vaginalis* ATCC BAA-1154

ArgA	**v**	PheA	v	**GLYG**	**+**	BGALi	v	**MTE**	**v**
GGT	**–**	ProA	**+**	**dMNE**	**v**	ODC	v	**IGLM**	**–**
LysA	**v**	PryA	**–**	**dMAL**	**v**	AARA	v	**PHOS**	**–**
dGAL	**v**	TyrA	v	**SAC**	**v**	PVATE	v	**dRIB2**	**v**
LeuA	**+**	APPA	**+**	**NAG**	**–**	PHC	**–**	**OPS**	**–**
ELLM	**v**	dGLU	v	**URE**	**–**	dMLT	v	**dXYL**	**v**

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Table 4-8: *QC Organism: *Haemophilus aphrophilus* ATCC 33389

ArgA	**–**	PheA	**+**	**GLYG**	**–**	BGALi	**+**	**MTE**	**+**
GGT	**v**	ProA	**–**	**dMNE**	**+**	ODC	–	**IGLM**	**–**
LysA	**v**	PryA	**–**	**dMAL**	**v**	AARA	**+**	**PHOS**	**+**
dGAL	**v**	TyrA	v	**SAC**	**+**	PVATE	**–**	**dRIB2**	**v**
LeuA	**+**	APPA	**–**	**NAG**[1]	**v**	PHC	v	**OPS**	**v**
ELLM	**+**	dGLU	**+**	**URE**	**–**	dMLT	**+**	**dXYL**	**–**

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

[1]*Haemophilus aphrophilus* reaction for NAG is usually positive; however, it is rare but possible that a negative reaction will occur.

Table 4-9: Recommended QC Organism: *Haemophilus influenzae* ATCC 9007

ArgA	**v**	PheA	**+**	**GLYG**	**–**	BGALi	–	**MTE**	**–**
GGT	**–**	ProA	–	**dMNE**	**–**	ODC	–	**IGLM**	**–**
LysA	**v**	PryA	–	**dMAL**	**–**	AARA	–	**PHOS**	**+**
dGAL	**+**	TyrA	v	**SAC**	**–**	PVATE	–	**dRIB2**	**+**
LeuA	**+**	APPA	–	**NAG**	**v**	PHC	**+**	**OPS**	**+**
ELLM	**+**	dGLU	**+**	**URE**	**+**	dMLT	**+**	**dXYL**	**+**

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Table 4-10: *QC Organism: *Neisseria gonorrhoeae* ATCC 19424

ArgA	**v**	PheA	+	**GLYG**	**–**	BGALi	v	**MTE**	**–**
GGT	**–**	ProA	+	**dMNE**	**–**	ODC	–	**IGLM**	**–**
LysA	**v**	PryA	–	**dMAL**	**–**	AARA	**–**	**PHOS**	**–**
dGAL	**–**	TyrA	v	**SAC**	**–**	PVATE	v	**dRIB2**	**–**
LeuA	**+**	APPA	v	**NAG**	**–**	PHC	**–**	**OPS**	**–**
ELLM	**–**	dGLU	v	**URE**	**–**	dMLT	**–**	**dXYL**	**–**

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Table 4-11: *QC Organism: *Neisseria lactamica* ATCC 23970

ArgA	**v**	PheA	+	**GLYG**	**–**	BGALi	+	**MTE**	**–**
GGT	**–**	ProA	+	**dMNE**	**–**	ODC	–	**IGLM**	**v**
LysA	**–**	PryA	**–**	**dMAL**	**+**	AARA	+	**PHOS**	–
dGAL	**–**	TyrA	v	**SAC**	**–**	PVATE	v	**dRIB2**	**–**
LeuA	**+**	APPA	v	**NAG**	**–**	PHC	**–**	**OPS**	**–**
ELLM	**v**	dGLU	+	**URE**	**–**	dMLT	v	**dXYL**	**–**

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Table 4-12: *QC Organism: *Oligella urethralis* ATCC 17960

ArgA	**–**	PheA	+	**GLYG**	**–**	BGALi	v	**MTE**	**–**
GGT	**+**	ProA	+	**dMNE**	**–**	ODC	v	**IGLM**	**v**
LysA	**v**	PryA	**–**	**dMAL**	**–**	AARA	v	**PHOS**	**–**
dGAL	**–**	TyrA	+	**SAC**	**–**	PVATE	+	**dRIB2**	**–**
LeuA	**+**	APPA	**v**	**NAG**	**–**	PHC	v	**OPS**	**v**
ELLM	**+**	dGLU	**–**	**URE**	**–**	dMLT	+	**dXYL**	**–**

+ = 95% to 100% positive; v = 6% to 94% positive; – = 0% to 5% positive.

Limitations

Do not use the VITEK® 2 NH cards with direct clinical samples or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

Newly described or rare species may not be included in the NH database. Selected species will be added as strains become available. Testing of unclaimed species may result in an unidentified result or a misidentification.

Performance Characteristics

In a recent multi-site clinical study, the performance of the VITEK® 2 NH was evaluated using 371 clinical and stock isolates of both commonly and rarely observed species of fastidious organisms. The reference identification was determined by 16S rRNA gene sequencing. Overall, the VITEK® 2 NH correctly identified 96.5% of these isolates, including 10.2% low discrimination with the correct species listed. Misidentifications occurred at 2.7% and no identifications occurred at 0.8%

Organisms Identified by the NH Card

- *Actinobacillus ureae*
- *Campylobacter coli*
- *Campylobacter fetus* ssp. *fetus*
- *Campylobacter jejuni* ssp. *jejuni*
- *Capnocytophaga* spp.
- *Cardiobacterium hominis*
- *Eikenella corrodens*
- *Gardnerella vaginalis*
- *Haemophilus actinomycetemcomitans*
- *Haemophilus aphrophilus/paraphrophilus*
- *Haemophilus haemolyticus*
- *Haemophilus influenzae*
- *Haemophilus parahaemolyticus*
- *Haemophilus parainfluenzae*
- *Haemophilus segnis*
- *Kingella denitrificans*
- *Kingella kingae*
- *Moraxella (Branhamella) catarrhalis*
- *Neisseria cinerea*

- *Neisseria elongata*
- *Neisseria gonorrhoeae*
- *Neisseria lactamica*
- *Neisseria meningitidis*
- *Neisseria sicca*
- *Oligella urethralis*
- *Suttonella indologenes*

NH Well Contents

Table 4-13: NH Well Contents

Well #	Test	Mnemonic	Amount/Well
1	Arginine ARYLAMIDASE	ArgA	0.0324 mg
2	GAMMA-GLUTAMYL-TRANSFERASE	GGT	0.0228 mg
3	L-Lysine-ARYLAMIDASE	LysA	0.0228 mg
4	D-GALACTOSE	dGAL	0.3 mg
5	Leucine ARYLAMIDASE	LeuA	0.023 mg
6	ELLMAN	ELLM	0.03 mg
7	Phenylalanine ARYLAMIDASE	PheA	0.026 mg
8	L-Proline ARYLAMIDASE	ProA	0.023 mg
10	L-Pyrrolydonyl-ARYLAMIDASE	PyrA	0.018 mg
13	Tyrosine ARYLAMIDASE	TyrA	0.0279 mg
15	Ala-Phe-Pro-ARYLAMIDASE	APPA	0.038 mg
18	D-GLUCOSE	dGLU	0.3 mg
19	GLYCOGENE	GLYG	0.18 mg
20	D-MANNOSE	dMNE	0.3 mg
22	D-MALTOSE	dMAL	0.3 mg
28	SACCHAROSE/SUCROSE	SAC	0.3 mg
33	N-ACETYL-D-GLUCOSAMINE	NAG	0.3 mg
36	UREASE	URE	0.15 mg
39	BETA-GALACTOPYRANOSIDASE Indoxyl	BGALi	0.006 mg
40	ORNITHINE DECARBOXYLASE	ODC	0.15 mg
41	ALPHA-ARABINOSIDASE	AARA	0.0324 mg
45	PYRUVATE	PVATE	0.15 mg
46	PHOSPHORYL CHOLINE	PHC	0.0366 mg
47	D-MALATE	dMLT	0.15 mg
51	MALTOTRIOSE	MTE	0.3 mg
52	L-GLUTAMINE	IGLM	0.15 mg
59	PHOSPHATASE	PHOS	0.05 mg
61	D-Ribose 2	dRIB2	0.3 mg

Table 4-13: NH Well Contents

Well #	Test	Mnemonic	Amount/Well
62	Phenylphosphonate	OPS	0.024 mg
64	D-XYLOSE	dXLY	0.3 mg

Note: *Other well numbers between 1 and 64 not designated in this table are empty.*

NH Supplemental Tests

Table 4-14: NH Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
CAT	CATALASE	Colony placed on a drop of hydrogen peroxide produces gas bubbles. The bacteria that contain cytochrome enzyme are catalase positive.		6,10
COCCI	COCCUS SHAPE	Coccus (round) shape of the bacterial cell examined with gram stain.		6,10
42C	Growth at 42 °C	Ability of certain species to grow at 42 °C.		10
AGAR 35C	Growth at 35 °C (nutrient agar)	Ability of certain species to grow at 35 °C on nutrient agar.		9,10
25C	Growth at 25 °C	Ability of certain species to grow at 25 °C.		10
DNAse	DNAse	Ability of certain species to produce DNAse resulting in the degradation of DNA.		9,10
ESCULIN	ESCULIN hydrolysis	Hydrolysis of esculin forms esculetin that produces a black pigment in the presence of iron salts.		6,10
HEMO-horse	Horse blood hemolysis	Certain species possess hemolysins that give a transparent zone around the colonies on blood-based agars.	Hemolysis on horse blood is used as a differential test in the identification of *Haemophilus* spp.	10

Table 4-14: NH Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
HIP	HIPPURATE hydrolyse	Hydrolysis of sodium hippurate releases glycine that produces a blue colored product after addition of ninhydrin.	Of the *Campylobacter* species, only *Campylobacter jejuni* gives a positive hippurate reaction.	10
IND	INDOLE	Ability of certain species to split indole from tryptophan detected by a colored product revealed with a specific reagent (e.g., Kovacs, Ehrlichs, DMAC reagents, etc.)		6,10,13
MOB	MOTILITY	Test for motility using hanging drop procedure or saline mount.	Bacterial motility can be observed by placing a drop of bacterial suspension on a slide and viewing it under a microscope.	10,13
NO3	NITRATE REDUCTION	Test for the ability to reduce nitrate to nitrite or nitrogen gas.		6,10,13
ONPG	BETA-GALACTOSIDASE	Presence of beta-galactosidase cleaves o-nitrophenol-beta-D-galactopyranoside to produce a yellow colored product.		5,6,9,10
OX	OXIDASE	Detection of the presence of cytochrome C.		6,10
THAYER M.	Thayer Martin Agar	Growth on selective medium used in the differentiation of *Neisseria* spp.	Thayer Martin Agar, New York City Agar, or Chocolate Polyvitex Agar with VCAT can be used for this test.	6,10

Table 4-14: NH Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
UREASE	Urease	Hydrolysis of urea releases ammonia resulting in alkalinization of the medium observed with a pH indicator (e.g., red color formation in the presence of phenol red).	Some tests also appear on the NH card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	6,10
V FACTOR	V FACTOR (NAD) REQUIREMENT	NAD required for growth.		9,10
X FACTOR	X FACTOR (HEMIN) REQUIREMENT	Hemin required for growth.		6,10
dFRUCTOSE	D-FRUCTOSE acidification	Acidification of carbon source observed with pH indicator (e.g., phenol red, bromocresol purple, etc.)	Some tests also appear on the NH card but are recommended as supplemental tests since results of conventional macromethods often differ from rapid commercial micromethods.	4,6,10,13
dGALACTOSE	D-GALACTOSE acidification			
dGLUCOSE	D-GLUCOSE acidification			
LACTOSE	LACTOSE acidification			
dMALTOSE	D-MALTOSE acidification			
dMANNITOL	D-MANNITOL acidification			
dMANNOSE	D-MANNOSE acidification			
dRAFFINOSE	D-RAFFINOSE acidification			
SACCHAROSE	SACCHAROSE/SUCROSE acidification			
dTREHALOSE	D-TREHALOSE acidification			

Culture Requirements Table

Table 4-15: Culture Requirements

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	Inoculum Density	Manual Dilution for AST	Age of Suspension Before Loading Instrument
NH	Campylobacter: TSAB[1] Fastidious: CHOC[1] CHOC PVX[1]	Campylobacter: 18 to 24 hours Fastidious: 18 to 24 hours	Campylobacter: 35 °C to 37 °C microaerophilic conditions Fastidious: 35 °C to 37 °C with 5% to10% CO_2	2.70 – 3.30 McFarland Standard	N/A	≤ 30 minutes

[1]These media were used in the identification product database developments and will give optimal performance.

Culture Requirements Table — Media Abbreviations

CHOC = Chocolate agar
CHOC PVX = Chocolate Polyvitex agar
TSAB = Trypticase Soy Agar with 5% sheep blood

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bioMérieux, Inc.

Use this Product Information with VITEK® 2 Product No. 21346.

bioMérieux, Inc.
Box 15969,
Durham, North Carolina 27704-0969 USA
tel. (1) 800-682-2666

EC REP

bioMérieux SA
au capital de 11 879 045 €
673 620 399 RCS LYON
69280 Marcy-l'Etoile/ France
tél. 33 (0)4 78 87 20 00
fax 33 (0)4 78 87 20 90
http://www.biomerieux.com

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BCL Product Information 5

Intended Use

The VITEK® 2 *Bacillus* identification card (BCL) is intended for use with VITEK® 2 systems for the automated identification of aerobic endospore-forming organisms of the family *Bacillaceae*. The VITEK® 2 BCL identification card is a single-use disposable. For a list of claimed species, see Organisms Identified by the BCL Card on page 5-14.

Description

The BCL card is based on established biochemical methods (1-7) and on newly developed substrates. There are 46 biochemical tests measuring carbon source utilization, inhibition and resistance, and enzymatic activities. Final identification results are available in approximately 14 hours.

The database for the BCL card was developed using an extensive library of well characterized stock cultures. A fresh isolate study was not undertaken due to the difficulty in obtaining sufficient fresh isolates for statistical relevance.

For a list of well contents, see BCL Well Contents on page 5-16.

Precautions

- Suspensions not within the appropriate zone on the VITEK 2 DENSICHEK™ may compromise card performance.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner is damaged or if no desiccant is present.
- Allow the card to come to room temperature before opening the package liner.
- Do not use powdered gloves. Powder may interfere with the optics.
- Use of culture media other than the recommended types must be validated by the customer laboratory for acceptable performance.

- A Gram stain should be performed to determine an organism's Gram reaction and morphology prior to selecting which identification card to inoculate.
- The card performs as intended only when used in conjunction with VITEK® 2 systems.
- **Do not use glass test tubes**. Use clear plastic (polystyrene) test tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Ensure that cards are filled properly and do not load any cards that are filled improperly. Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the vacuum fill.
- Give special consideration to sample source.
- Interpretation of test results requires the judgment and skill of a person knowledgeable in microbial identification testing. Additional testing may be required.

WARNING

All microbial cultures are potentially infectious and should be treated with universal precautions (12,13).

Storage and Handling

Upon receipt, store VITEK® 2 BCL cards unopened in their original package liner at 2 °C to 8 °C.

Specimen Preparation

For specimen preparation information, see the Culture Requirements Table on page 5-23.

Materials

When used with VITEK® 2 instrumentation, the BCL card is a complete system for routine identification testing of aerobic endospore-forming organisms of the family *Bacillaceae*. Required materials are:

- VITEK® 2 BCL Card
- VITEK 2 DENSICHEK™
- VITEK 2 DENSICHEK™ Power Adapter
- Lithium Battery for DENSICHEK
- DENSICHEK Calibrator
- VITEK® 2 Cassette
- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- 12 x 75 mm clear plastic (polystyrene) disposable test tubes
- Sterile sticks or swabs
- Appropriate agar medium (See Culture Requirements Table on page 5-23.)

Optional accessories:

- Saline Dispensers
- Pre-dispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Procedure

For product-specific information, see Culture Requirements Table on page 5-23.

Note: *Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.*

1) Select isolated colonies from a primary plate if culture requirements are met,

or
Subculture organism to be tested to appropriate agar medium and incubate accordingly.

2) Aseptically transfer 3.0 mL of sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 x 75 mm).

3) Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare the homogenous organism suspension with a density equivalent to a McFarland No. 1.80 to 2.20 using a calibrated VITEK 2 DENSICHEK™.

Note: *Age of suspension must not exceed 30 minutes before inoculating card.*

4) Place the suspension tube and BCL card in the cassette.

5) Refer to the User Manuals for the VITEK® 2 Instruments for instructions on data entry and how to load the cassette into the instrument.

6) Follow your local inspecting agency's guidelines for the disposal of hazardous waste.

Results

Identification Analytical Techniques

The identification of an organism using the VITEK® 2 systems uses a methodology based on the characteristics of the data and knowledge about the organism and reactions being analyzed. Sufficient data have been collected from known strains to estimate the typical reactions of the claimed species to a set of discriminating biochemicals. If a unique identification pattern is not recognized, a list of possible organisms is given, or the strain is determined to be outside the scope of the database.

The printed lab report contains suggestions for any supplemental tests necessary to complete the identification. If the tests are not sufficient to complete the identification, then standard microbiology references and literature should be consulted.

Certain species may belong to a slashline (mixed) taxa identification. This occurs when the biopattern is the same for the taxa listed.

Supplemental tests may be used to separate slashline taxa. The following species belong to the slashline taxa:

Table 5-1: Slashline (mixed) Taxa Identification

Slashline Name	Species Belonging to the Slashline
Bacillus cereus/Bacillus thuringiensis	*Bacillus cereus* *Bacillus thuringiensis*
Bacillus sphaericus/Bacillus fusiformis	*Bacillus fusiformis* *Bacillus sphaericus*
Bacillus subtilis/Bacillus amyloliquefaciens	*Bacillis amyloliquefaciens* *Bacillus subtilis*
Geobacillus thermoglucosidasius/Geob. thermodenitrificans	*Geobacillus thermodenitrificans* *Geobacillus thermoglucosidasius*

Certain species may belong to a pseudoslashline (mixed) taxa identification. A pseudoslashline indicates a rare isolate or rare occurrence of the same biopattern. Supplemental tests may be used to separate pseudoslashline taxa. The following species belong to the pseudoslashline taxa:

Table 5-2: Pseudoslashline Taxa

Pseudoslashline Name	Species Belonging to the Pseudoslashline
Brevibacillus brevis/(Brevibacillus agri)	*Brevibacillus agri* *Brevibacillus brevis*
Paenibacillus glucanolyticus/(Bacillus circulans)	*Bacillus circulans* *Paenibacillus glucanolyticus*
Paenibacilllus pabuli/(Paenibacillus polymyxa)	*Paenibacillus pabuli* *Paenibacillus polymyxa*

Identification Card Qualifying Messages

Table 5-3: Identification Card Qualifying Messages

ID Message Confidence Level	Choices	% Probability	Comments
Excellent	1	96 to 99	
Very Good	1	93 to 95	
Good	1	89 to 92	
Acceptable	1	85 to 88	
Low Discrimination	2 to 3	Sum of choices = 100; after resolution to one choice, percent probability reflects the number associated with selected choice.	2 to 3 taxa exhibit same biopattern. Separate by supplemental testing.
Unidentified Organism	> 3 or 0	n/a	Either > 3 taxa exhibit same biopattern or Very atypical biopattern. Does not correspond to any taxon in the database. Check Gram stain and purity.

Percent Probability

As part of the identification process, the software compares the test set of reactions to the expected set of reactions of each organism, or organism group, that can be identified by the product. A quantitative value, the percent probability, is calculated and relates to how well the observed reactions compare to the typical reactions of each organism. A perfect match between the test reaction pattern and the unique reaction pattern of a single organism, or organism group, would provide a percent probability of 99. When a perfect match is not obtained, it is still possible for the reaction pattern to be sufficiently close to that of an expected reaction pattern such that a clear decision can be provided about the organism identification. The range of percent probabilities in the one-choice case is 85 to 99. Values closer to 99 indicate a closer match to the typical pattern for the given organism.

When the reaction pattern is not sufficient to discriminate between two to three organisms, the percent probabilities reflect this ambiguity. The reported probability values indicate, relatively, the order in which the reaction pattern best corresponds to the listed possibilities. The order does not, however, suggest that the pattern match to one of the possible identifications is clearly superior to another. The probability characteristic of an overall sum of 100 is retained through the calculation process. After resolution to one choice, the probability characteristic of the single choice is retained.

Additional Information on the Lab Report

Supplemental test—External test that allows the user to resolve a slashline or Low Discrimination identification.

Contraindicating test—Test result that is unusual for a reported taxon.

Notes associated with certain taxa

Table 5-4: Notes associated with certain taxa

Note	Taxa
Possibility of Aneurinibacillus migulanus	*Aneurinbacillus aneurinilyticus*
Important! *Presumptive Indentification*	*Bacillus anthracis*

Notes associated with an improperly filled card or with a negative profile (biopattern)

- For the case where the instrument determines that the card has not been filled:
  "Terminated card—no organism suspension detected."
- For the case where the time between two readings is higher than 40 minutes:
  "CARD ERROR—Missing data."
- For the case where there is a negative profile:
  "Organism with low reactivity biopattern—please check viability."
- When a biopattern is calculated for an unknown organism that is completely negative or consists of both negative tests and tests that fall within the uncertainty zone, the identification call will be "Nonreactive biopattern."

The following species could potentially trigger this note if a test was atypical or fell within the uncertainty zone:

Table 5-5: Non-Reactive Species

Geobacillus thermodenitrificans
Geobacillus thermoglucosidasius

Quality Control

Quality control organisms and their expected results are listed in the VITEK® 2 BCL Quality Control Table and should be processed according to the procedure for test isolates outlined in this document. The BCL card will identify the quality control organisms as one-choice, within a low discrimination, or slashline identification. See the Quality Control Section for more details.

Frequency of Testing

Currently, it is recommended to use your most stringent inspecting agency's guidelines for frequency of identification product testing.

Common practice is to perform QC upon receipt of shipment of the test kits. Reactions must follow Online Product Information results.

If the results do not meet the criteria, subculture for purity and repeat test. If discrepant results are repeated, perform an alternate identification method.

Testing and Storage of QC Organisms

- Rehydrate organism according to the manufacturer's instructions.
- Streak organism onto TSA.
- Incubate for 18 to 24 hours.
- Mesophilic species: Organisms are incubated at 35 °C to 37 °C.
- Thermophilic species: Organisms are incubated at 54 °C to 56 °C.
- Check for purity. Perform second subculture for testing.

Storage Conditions

Short-Term Storage

1) Streak to a TSA plate or slant.

2) Incubate for 24 hours at 35 °C to 37 °C (or 54 °C to 56 °C for thermophiles).

3) Refrigerate at 2 °C to 8 °C for up to one week.

4) Subculture once as described above and use for QC.

Long-Term Storage

1) Make a heavy suspension in Trypticase Soy Broth with 15% glycerol
or
Inoculate a slant of TSA supplemented with 5 mg/L $MnSO_4$ (to enhance sporulation) and incubate until spores are observed by microscopy.

2) Freeze the broth culture at -70 °C
or
Refrigerate agar slants at 2 °C to 8 °C.

3) Subculture to TSA twice before running QC.

Note: *Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.*

BCL Quality Control Table

Aneurinibacillus aneurinilyticus **ATCC® 11376 / LMG 12387**
Bacillus circulans **ATCC 61 / LMG 16633**
Bacillus licheniformis **ATCC 12759 / LMG 7560**
Brevibacillus agri **ATCC 51663 / LMG 15103**
Brevibacillus laterosporus **ATCC 64 / LMG 16000**
Geobacillus stearothermophilus **ATCC 12978 / LMG 21890**
Paenibacillus macerans **ATCC 8509 / LMG 21891**
Paenibacillus polymyxa **ATCC 7070 / LMG 21892**
Virgibacillus pantothenticus **ATCC 14576 / LMG 7129**

The following organisms marked with an asterisk indicate additional quality control if required by local regulatory agencies.

Table 5-6: *QC Organism: *Aneurinibacillus aneurinilyticus* ATCC 11376 / LMG 12387

BXYL	**v**	AGAL	v	**INO**	**–**	dMNE	v	**PVATE**	**v**	NaCl 6.5%	–
LysA	**v**	AlaA	v	**MdG**	**–**	dMLZ	–	**AGLU**	**–**	KAN	+
AspA	**v**	TyrA	v	**ELLM**	**v**	NAG	–	**dTAG**	**–**	OLD	–
LeuA	**v**	BNAG	v	**MdX**	**–**	PLE	–	**dTRE**	**–**	ESC	v
PheA	**v**	APPA	v	**AMAN**	**v**	IRHA	–	**INU**	**v**	TTZ	v
ProA	**–**	CDEX	–	**MTE**	**–**	BGLU	v	**dGLU**	**–**	POLYB_R	+
BGAL	**v**	dGAL	–	**GlyA**	**v**	BMAN	–	**dRIB**	**v**		
PyrA	**–**	GLYG	–	**dMAN**	**–**	PHC	v	**PSCNa**	**+**		

+ = 95% to 100% positive; v = 6% to 94% positive; - = 0% to 5% positive

Table 5-7: *QC Organism: *Bacillus circulans* ATCC 61 / LMG 16633

BXYL	**+**	AGAL	+	**INO**	**v**	dMNE	+	**PVATE**	**v**	NaCl 6.5%	v
LysA	**–**	AlaA	v	**MdG**	**+**	dMLZ	+	**AGLU**	**+**	KAN	v
AspA	**+**	TyrA	+	**ELLM**	**v**	NAG	+	**dTAG**	**–**	OLD	v
LeuA	**+**	BNAG	v	**MdX**	**v**	PLE	v	**dTRE**	**v**	ESC	+
PheA	**+**	APPA	+	**AMAN**	**+**	IRHA	v	**INU**	**+**	TTZ	v
ProA	**+**	CDEX	v	**MTE**	**+**	BGLU	v	**dGLU**	**+**	POLYB_R	v
BGAL	**+**	dGAL	+	**GlyA**	**–**	BMAN	+	**dRIB**	**v**		
PyrA	**v**	GLYG	+	**dMAN**	**v**	PHC	–	**PSCNa**	**v**		

+ = 95% to 100% positive; v = 6% to 94% positive; - = 0% to 5% positive

Table 5-8: Recommended QC Organism: *Bacillus licheniformis* ATCC 12759 / LMG 7560

BXYL	**+**	AGAL	v	**INO**	**+**	dMNE	+	**PVATE**	**+**	NaCl 6.5%	+
LysA	**v**	AlaA	v	**MdG**	**+**	dMLZ	–	**AGLU**	**v**	KAN	v
AspA	**–**	TyrA	+	**ELLM**	**+**	NAG	+	**dTAG**	**+**	OLD	+
LeuA	**v**	BNAG	v	**MdX**	**–**	PLE	+	**dTRE**	**+**	ESC	+
PheA	**+**	APPA	v	**AMAN**	**v**	IRHA	v	**INU**	**v**	TTZ	v
ProA	**–**	CDEX	+	**MTE**	**+**	BGLU	+	**dGLU**	**+**	POLYB_R	v
BGAL	**+**	dGAL	v	**GlyA**	**v**	BMAN	v	**dRIB**	**v**		
PyrA	**+**	GLYG	v	**dMAN**	**+**	PHC	v	**PSCNa**	**–**		

+ = 95% to 100% positive; v = 6% to 94% positive; - = 0% to 5% positive

Table 5-9: *QC Organism: *Brevibacillus agri* ATCC 51663 / LMG 15103

BXYL	–	AGAL	v	**INO**	–	dMNE	–	**PVATE**	v	NaCl 6.5%	–
LysA	v	AlaA	v	**MdG**	v	dMLZ	–	**AGLU**	v	KAN	v
AspA	v	TyrA	+	**ELLM**	+	NAG	–	**dTAG**	–	OLD	–
LeuA	+	BNAG	+	**MdX**	–	PLE	v	**dTRE**	v	ESC	v
PheA	+	APPA	+	**AMAN**	v	IRHA	–	**INU**	v	TTZ	v
ProA	+	CDEX	v	**MTE**	v	BGLU	v	**dGLU**	–	POLYB_R	+
BGAL	v	dGAL	–	**GlyA**	v	BMAN	v	**dRIB**	v		
PyrA	+	GLYG	–	**dMAN**	+	PHC	+	**PSCNa**	v		

+ = 95% to 100% positive; v = 6% to 94% positive; - = 0% to 5% positive

Table 5-10: *QC Organism: *Brevibacillus laterosporus* ATCC 64 / LMG 16000

BXYL	v	AGAL	–	**INO**	–	dMNE	v	**PVATE**	v	NaCl 6.5%	–
LysA	–	AlaA	–	**MdG**	v	dMLZ	–	**AGLU**	–	KAN	v
AspA	v	TyrA	–	**ELLM**	v	NAG	–	**dTAG**	–	OLD	v
LeuA	v	BNAG	v	**MdX**	–	PLE	–	**dTRE**	v	ESC	v
PheA	–	APPA	v	**AMAN**	v	IRHA	–	**INU**	v	TTZ	v
ProA	v	CDEX	–	**MTE**	–	BGLU	v	**dGLU**	v	POLYB_R	+
BGAL	v	dGAL	–	**GlyA**	v	BMAN	–	**dRIB**	v		
PyrA	+	GLYG	–	**dMAN**	v	PHC	v	**PSCNa**	v		

+ = 95% to 100% positive; v = 6% to 94% positive; - = 0% to 5% positive

Table 5-11: *QC Organism: *Geobacillus stearothermophilus* ATCC 12978 / LMG 21890

BXYL	–	AGAL	v	**INO**	–	dMNE	v	**PVATE**	–	NaCl 6.5%	–
LysA	–	AlaA	v	**MdG**	–	dMLZ	v	**AGLU**	v	KAN	v
AspA	v	TyrA	+	**ELLM**	v	NAG	–	**dTAG**	–	OLD	v
LeuA	v	BNAG	–	**MdX**	–	PLE	v	**dTRE**	–	ESC	–
PheA	+	APPA	v	**AMAN**	–	IRHA	–	**INU**	–	TTZ	–
ProA	–	CDEX	v	**MTE**	v	BGLU	–	**dGLU**	–	POLYB_R	–
BGAL	–	dGAL	–	**GlyA**	–	BMAN	–	**dRIB**	–		
PyrA	v	GLYG	–	**dMAN**	–	PHC	–	**PSCNa**	v		

+ = 95% to 100% positive; v = 6% to 94% positive; - = 0% to 5% positive.
This organism grows at 54 °C to 56 °C.

Table 5-12: *QC Organism: *Paenibacillus macerans* ATCC 8509 / LMG 21891

BXYL	+	AGAL	+	**INO**	–	dMNE	v	**PVATE**	v	NaCl 6.5%	–
LysA	–	AlaA	v	**MdG**	+	dMLZ	+	**AGLU**	v	KAN	+
AspA	v	TyrA	+	**ELLM**	+	NAG	–	**dTAG**	–	OLD	v
LeuA	+	BNAG	v	**MdX**	+	PLE	v	**dTRE**	+	ESC	+
PheA	+	APPA	v	**AMAN**	v	IRHA	+	**INU**	+	TTZ	v
ProA	–	CDEX	+	**MTE**	+	BGLU	+	**dGLU**	+	POLYB_R	v
BGAL	+	dGAL	+	**GlyA**	–	BMAN	v	**dRIB**	v		
PyrA	–	GLYG	+	**dMAN**	+	PHC	–	**PSCNa**	v		

+ = 95% to 100% positive; v = 6% to 94% positive; - = 0% to 5% positive

Table 5-13: *QC Organism: *Paenibacillus polymyxa* ATCC 7070 / LMG 21892

BXYL	+	AGAL	+	**INO**	–	dMNE	+	**PVATE**	v	NaCl 6.5%	v
LysA	–	AlaA	–	**MdG**	+	dMLZ	–	**AGLU**	v	KAN	v
AspA	v	TyrA	+	**ELLM**	–	NAG	–	**dTAG**	–	OLD	v
LeuA	+	BNAG	v	**MdX**	v	PLE	+	**dTRE**	v	ESC	+
PheA	v	APPA	v	**AMAN**	–	IRHA	–	**INU**	v	TTZ	+
ProA	–	CDEX	v	**MTE**	+	BGLU	+	**dGLU**	+	POLYB_R	+
BGAL	+	dGAL	+	**GlyA**	–	BMAN	v	**dRIB**	+		
PyrA	–	GLYG	+	**dMAN**	+	PHC	–	**PSCNa**	v		

+ = 95% to 100% positive; v = 6% to 94% positive; - = 0% to 5% positive

Table 5-14: *QC Organism: *Virgibacillus pantothenticus* ATCC 14576 / LMG 7129

BXYL	–	AGAL	v	**INO**	–	dMNE	v	**PVATE**	v	NaCl 6.5%	v
LysA	+	AlaA	+	**MdG**	v	dMLZ	v	**AGLU**	+	KAN	–
AspA	v	TyrA	+	**ELLM**	v	NAG	–	**dTAG**	v	OLD	v
LeuA	v	BNAG	+	**MdX**	–	PLE	v	**dTRE**	v	ESC	+
PheA	+	APPA	v	**AMAN**	v	IRHA	v	**INU**	v	TTZ	v
ProA	–	CDEX	v	**MTE**	v	BGLU	+	**dGLU**	v	POLYB_R	–
BGAL	v	dGAL	v	**GlyA**	v	BMAN	v	**dRIB**	+		
PyrA	v	GLYG	v	**dMAN**	–	PHC	v	**PSCNa**	v		

+ = 95% to 100% positive; v = 6% to 94% positive; - = 0% to 5% positive

Limitations

The VITEK® 2 BCL card cannot be used with direct microbial samples or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

Newly described or rare species may not be included in the BCL database. Selected species will be added as strains become available. Testing of unclaimed species may result in an unidentified result or a misidentification.

The reaction profile contained in the identification database for *Bacillus anthracis* is based on cultures grown for 15 to18 hours on Trypticase Soy Agar. Cultivation on other media or at different incubation times may affect the results.

Performance Characteristics

The database performance of the VITEK® 2 BCL was evaluated using 1436 isolates of both commonly and rarely observed species of Gram-positive aerobic spore-forming bacilli.* The reference identification was determined with the api® 50CHB identification kit and other conventional test methods. Overall, the VITEK® 2 BCL correctly identified 96.1% of the isolates, including 9.3% low discrimination with the correct species listed. Misidentifications occurred at 2.6% and no identifications occurred at 1.3%.

* Data on file at bioMérieux, Inc.

Organisms Identified by the BCL Card

- Aneurinibacillus aneurinilyticus
- *Bacillus amyloliquefaciens*
- *Bacillus anthracis*
- *Bacillus badius*
- *Bacillus cereus*
- *Bacillus circulans*
- *Bacillus coagulans*
- *Bacillus firmus*
- *Bacillus fusiformis*
- *Bacillus lentus*
- *Bacillus licheniformis*
- *Bacillus megaterium*
- *Bacillus mycoides*
- *Bacillus pumilus*
- *Bacillus smithii*
- *Bacillus sphaericus*
- *Bacillus sporothermodurans*
- *Bacillus subtilis*
- *Bacillus thuringiensis*
- *Brevibacillus agri*
- *Brevibacillus borstelensis*
- *Brevibacillus brevis*
- *Brevibacillus centrosporus*
- *Brevibacillus choshinensis*
- *Brevibacillus invocatus*
- *Brevibacillus laterosporus*
- *Brevibacillus parabrevis*
- *Geobacillus stearothermophilus*
- *Geobacillus thermodenitrificans*
- *Geobacillus thermoglucosidasius*
- *Paenibacillus alvei*
- *Paenibacillus amylolyticus*
- *Paenibacillus durus* (formerly known as *Paenibacillus azotofixans)*
- *Paenibacillus glucanolyticus*
- *Paenibacillus macerans*
- *Paenibacillus pabuli*
- *Paenibacillus peoriae*
- *Paenibacillus polymyxa*
- *Paenibacillus thiaminolyticus*

- *Paenibacillus validus*
- *Virgibacillus pantothenticus*
- *Virgibacillus proomii*

BCL Well Contents

Table 5-15: BCL Well Contents

Well	Test	Mnemonic	Amount/Well
1	BETA-XYLOSIDASE	BXYL	0.0324 mg
3	L-Lysine-ARYLAMIDASE	LysA	0.0228 mg
4	L-Aspartate ARYLAMIDASE	AspA	0.024 mg
5	Leucine ARYLAMIDASE	LeuA	0.0234 mg
7	Phenylalanine ARYLAMIDASE	PheA	0.0264 mg
8	L-Proline ARYLAMIDASE	ProA	0.0234 mg
9	BETA-GALACTOSIDASE	BGAL	0.036 mg
10	L-Pyrrolydonyl-ARYLAMIDASE	PyrA	0.018 mg
11	ALPHA-GALACTOSIDASE	AGAL	0.036 mg
12	Alanine ARYLAMIDASE	AlaA	0.0222 mg
13	Tyrosine ARYLAMIDASE	TyrA	0.0282 mg
14	BETA-N-ACETYL-GLUCOSAMINIDASE	BNAG	0.0408 mg
15	Ala-Phe-Pro ARYLAMIDASE	APPA	0.0384 mg
18	CYCLODEXTRINE	CDEX	0.3 mg
19	D-GALACTOSE	dGAL	0.3 mg
21	GLYCOGENE	GLYG	0.1875 mg
22	myo-INOSITOL	INO	0.3 mg
24	METHYL-A-D-GLUCOPYRANOSIDE acidification	MdG	0.3 mg
25	ELLMAN	ELLM	0.03 mg
26	METHYL-D-XYLOSIDE	MdX	0.3 mg
27	ALPHA-MANNOSIDASE	AMAN	0.036 mg
29	MALTOTRIOSE	MTE	0.3 mg
30	Glycine ARYLAMIDASE	GlyA	0.012 mg
31	D-MANNITOL	dMAN	0.3 mg
32	D-MANNOSE	dMNE	0.3 mg
34	D-MELEZITOSE	dMLZ	0.3 mg
36	N-ACETYL-D-GLUCOSAMINE	NAG	0.3 mg
37	PALATINOSE	PLE	0.3 mg
39	L-RHAMNOSE	IRHA	0.3 mg
41	BETA-GLUCOSIDASE	BGLU	0.036 mg
43	BETA-MANNOSIDASE	BMAN	0.036 mg
44	PHOSPHORYL CHOLINE	PHC	0.0366 mg
45	PYRUVATE	PVATE	0.15 mg
46	ALPHA-GLUCOSIDASE	AGLU	0.036 mg

Table 5-15: BCL Well Contents

Well	Test	Mnemonic	Amount/Well
47	D-TAGATOSE	dTAG	0.3 mg
48	D-TREHALOSE	dTRE	0.3 mg
50	INULIN	INU	0.12 mg
53	D-GLUCOSE	dGLU	0.3 mg
54	D-RIBOSE	dRIB	0.3 mg
56	PUTRESCINE assimilation	PSCNa	0.201 mg
58	GROWTH IN 6.5% NaCl	NaCl 6.5%	1.95 mg
59	KANAMYCIN RESISTANCE	KAN	0.006 mg
60	OLEANDOMYCIN RESISTANCE	OLD	0.003 mg
61	ESCULIN hydrolyse	ESC	0.0225 mg
62	TETRAZOLIUM RED	TTZ	0.0189 mg
63	POLYMIXIN_B RESISTANCE	POLYB_R	0.00093 mg

Note: *Other well numbers between 1 and 64 not designated in this table are empty.*

BCL Supplemental Tests

Table 5-16: BCL Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
20C	Growth at 20 °C	Ability to grow at 20 °C.		1,2
2KGa	2-Keto-D-Gluconate assimilation	Ability to use 2-keto-D-gluconate.		5,6
50C	Growth at 50 °C	Ability to grow at 50 °C.		1,2
ANA.GROWTH	Anaerobic growth	Ability to grow in the absence of oxygen.		1,2,6
CASEIN	Casein hydrolysis	Ability to decompose casein.		1,2
CellChains	Cells occurring in chains	Microscopic examination for the presence of bacterial cells forming chains. Phase-contrast microscopy is recommended.		1,2,6
dARABINOSE	D-arabinose acidification	Acid produced from the fermentation of D-arabinose observed with pH indicator (e.g., phenol red, bromocresol purple, etc.)		1,2,3

Table 5-16: BCL Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
dFRUCTOSEa	D-Fructose assimilation	Ability to use D-fructose.		5,6
dMANNOSE	D-mannose acidification	Acid produced from the fermentation of D-mannose observed with pH indicator (e.g., phenol red, bromocresol purple, etc.)	Some tests also appear on the BCL card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods	1,2,3
dSORBITOL	D-sorbitol acidification	Acid produced from the fermentation of D-sorbitol observed with pH indicator (e.g., phenol red, bromocresol purple, etc.)		1,2,3,6
dTURANOSE	D-turanose acidification	Acid produced from the fermentation of D-turanose observed with pH indicator (e.g., phenol red, bromocresol purple, etc.)		1,2,3
Egg Yolk	Egg yolk agar	Detects the presence of the enzyme, lecithinase, which degrades egg-yolk (broth or agar) forming a heavy white precipitate.	*Bacillus cereus* group organisms (*B. anthracis*, *B. cereus*, *B. thuringiensis* and *B. mycoides*) can be differentiated from all other species, on the basis of a positive result for this test.	1,2,6

Table 5-16: BCL Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
ESCULIN	Esculin hydrolysis	Hydrolysis of esculin yields esculetin which forms a brown-black complex with ferric ions.		1,3
GELATIN	Gelatin hydrolysis	Liquefaction of gelatin is mediated by the proteolytic enzyme, gelatinase, releasing a black pigment which diffuses throughout the tube.		1,2,3,6
GRAM +	Gram positive	Differential stain used to demonstrate the staining properties of bacteria. Organisms stain Gram positive.	Only one organism on the BCL card stains Gram negative – *Brevibacillus invocatus*. All other organisms are Gram positive. Young cultures should always be used to avoid Gram variable results often obtained with older cultures (> 24 hours).	1,2,5,6
IND	Indole	Metabolism of tryptophan results in the production of indole which forms a pink-red color with p-dimethylaminobenzaldehyde (e.g., Kovac's reagent).		1,2

Table 5-16: BCL Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
LACTATEa	DL-lactate assimilation	Ability to use DL-lactate.		5,6
lRHAMNOSE	L-rhamnose acidification	Acid produced from the fermentation of L-rhamnose observed with pH indicator (e.g., phenol red, bromocresol purple, etc.)	Some tests also appear on the BCL card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods	1,2,3,6
MOB	Motility	Microscopic examination for the motility of cells (moving against the general flow of liquid under the cover-slip). Phase-contrast microscopy is recommended.		1,2
NaCl 5%	Growth in 5% NaCl	Ability to grow in the presence of 5% NaCl.	Some similar tests also appear on the BCL card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods	
NAGLN	N-acetyl-Glucosamine	Acid produced from the fermentation of N-acetyl-D-glucosamine, observed with pH indicator (e.g., phenol red, bromocresol purple, etc.)	Some tests also appear on the BCL card but are recommended as supplemental tests since results of conventional macromethods may differ from rapid commercial micromethods	1,2,3

Table 5-16: BCL Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
NO3	Nitrate reduction	Ability to reduce nitrates to nitrites or nitrogen gas. On the addition of reagents, a red coloration indicates presence of nitrites. A yellow color, remaining yellow after the addition of zinc dust, indicates the presence of Nitrogen gas. Gas bubbles may also be observed.		1,2,6
OX	Oxidase	Production of the enzyme cytochrome C oxidase.		1,2
RHIZOIDcol	Rhizoid Colonies	Observation of rhizoidal shaped colonies on agar.	*Bacillus mycoides* can be differentiated from *B. cereus* and *B. thuringiensis* by producing rhizoidal shaped colonies.	1,2,6
SPORANGEsw	Swollen Sporangia	Microscopic examination of Sporangia for swelling. Phase-contrast microscopy is recommended.		1,2,6
SPORE C	Spore central	Microscopic examination for spores situated in the center of the bacterial cell. Phase-contrast microscopy is recommended.		1,2,6
SPORE R	Spore round	Microscopic examination for round shaped spores. Phase-contrast microscopy is recommended.		1,2,6

Table 5-16: BCL Supplemental Tests

Abbreviation	Test Name	Description	Comments	Reference
SPORE T	Terminal spore	Microscopic examination for spores situated towards either terminal end of the bacterial cell. Phase-contrast microscopy is recommended.		1,2,6
TOX.CRYST.	Toxin crystal presence	Microscopic examination for the presence of parasporal crystals (insecticidal toxin crystals). Phase-contrast microscopy is recommended.	*Bacillus thuringiensis* is differentiated from *B. cereus* and *B. mycoides* by the production of crystals.	1,2,6
VP	Voges-Proskauer	Ability to produce acetoin from the fermentation of glucose.		1,2

Culture Requirements Table

Table 5-17: Culture Requirements

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	Inoculum Density	Dilution for AST	Age of Suspension Before Loading Instrument
BCL	TSA[1] CNT	18 to 24 hours[2]	Mesophilic species: 30 °C to 37° C aerobic non-CO_2 Thermophilic species: 54 °C to 56° C aerobic non-CO_2	1.80 to 2.20 McFarland Standard	N/A	≤ 30 minutes

[1] This medium was used in the identification product database developments and will give optimal performance.
[2] *Bacillus anthracis* strains must be tested using cultures grown for 15 to 18 hours (See the Limitations section).

Culture Requirements Table—Media abbreviations:

TSA = Trypticase Soy Agar

CNT = Count-TACT (irradiated) Trypticase Soy Agar

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bioMérieux, Inc.
Online Product Information (2005)
Use this Online Product Information
with VITEK® 2 Product No. 21345

bioMérieux, Inc.
Box 15969,
Durham, North Carolina 27704-0969 USA
tel. (1) 800.682.2666

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SUSCEPTIBILITY PRODUCT INFORMATION 6

Intended Use

The Antimicrobial Susceptibility Test (AST) card is intended for use with VITEK® 2 systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for most clinically significant aerobic gram-negative bacilli, *Staphylococcus* spp*., Enterococcus* spp*., Streptococcus agalactiae, S. pneumoniae,* and yeast.

Summary and Explanation of the Test

Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used agents. Isolated colonies of an organism that may play a pathogenic role are selected from an agar plate and tested for susceptibility. These tests are then examined and the Minimum Inhibitory Concentration (MIC) is determined. The MIC obtained using a dilution test may tell the physician the concentration of an antimicrobial agent needed at the site of infection to inhibit the infecting organism.

MICs have been determined traditionally using antimicrobial concentrations derived from serial twofold dilutions (5). The MIC is then determined from the lowest dilution that shows inhibition of growth. Interpretative criterion (Susceptible, Intermediate, or Resistant) can then be assigned to MIC results to aid in the direction of therapy.

For some antimicrobials (e.g., high-level gentamicin, high-level streptomycin) only a qualitative result is generated.

The standard and reference procedures are based on susceptibility tests requiring 16 to 24 hours of incubation. Various manufacturers have now developed automated procedures designed to generate results more rapidly by using shortened incubation times. Laboratories worldwide use either variations of the standard reference procedure or a commercially available product to determine the MICs of infectious organisms.

Extended-Spectrum Beta-Lactamases (ESBLs). ESBLs are enzymes that arise by mutations in genes for common plasmid-mediated beta-lactamases. Strains of *Klebsiella* spp. and *E. coli* that produce ESBLs may be clinically

resistant to therapy with penicillins, cephalosporins, or aztreonam despite apparent *in vitro* susceptibility to some of these agents. Some of these strains will show MICs above the normal susceptible population but below the standard breakpoints for certain extended-spectrum cephalosporins or aztreonam. Before reporting a strain as an ESBL producer, a confirmatory method should be performed. Please refer to the current Clinical and Laboratory Standards Institute (CLSI) guidance document for CLSI recommendations. According to the CLSI, for all confirmed ESBL producing strains, the test interpretation should be reported as resistant to all penicillins, cephalosporins, and aztreonam. The VITEK® 2 ESBL Test is a confirmatory test for those ESBLs that are inhibited by clavulanic acid. The VITEK® 2 ESBL Test utilizes cefotaxime, ceftazidime, and cefepime, with and without clavulanic acid, in determination of a positive or negative result.

Methicillin-Resistant Staphylococci (MRS). Resistance to oxacillin is used to detect the presence of MRS. Most MRS are usually also resistant to multiple antibiotics, including other beta-lactams, aminoglycosides, macrolides, clindamycin, and tetracycline.

Oxacillin (OX1). This test provides an MIC determination and category interpretation for oxacillin. Interpretative results for MRS will be reported as resistant to all cephems and other beta-lactams when the instrument is operating in the CLSI mode or the User-Defined (based on CLSI) mode. Results from this test correlate to results that would be obtained from standard dilution testing of oxacillin. This test reflects the CLSI breakpoints for coagulase-negative staphylococci and *S. aureus.*

Oxacillin MIC (OX). This test provides an MIC determination and category interpretation for oxacillin. Results from this test correlate to results that would be obtained from standard dilution testing of oxacillin. The default breakpoints used are for *Staphylococcus* species in CA-SFM mode.

Oxacillin Screen (OXS). This test predicts either a susceptible or resistant result for oxacillin when tested for *Staphylococcus* species. The test result correlates with results obtained from the agar screen method.

Cefoxitin Screen (OXSF). This test may be used to predict *mec*A-mediated oxacillin resistance, and it is based on the cefoxitin disk screen test. The cefoxitin screen and oxacillin work in combination to determine the final interpretation reported for oxacillin. Most methicillin-resistant staphylococci (MRS) are usually also resistant to multiple antibiotics, including other beta-lactams, aminoglycosides, macrolides, clindamycin, and tetracycline.

Synergy Screen. Since the use of penicillin or ampicillin alone often results in frequent failure in the treatment of serious enterococcal endocarditis, combination therapy is usually indicated to enhance bactericidal activity. The

synergy between a cell wall active agent (such as penicillin, ampicillin, or vancomycin) and an aminoglycoside (such as gentamicin, kanamycin or streptomycin) is best predicted for enterococci by screening for high-level resistance to the aminoglycoside. When enterococci are susceptible *in vitro* to the high-level aminoglycoside and a cell wall active agent, this is predictive of the effectiveness of this combination therapy. The VITEK® 2 systems results are reported as SYN-S (high-level synergy screen is susceptible) and SYN-R (high-level synergy screen is resistant).

VRSA Screen (VAS). This test may be used to predict the presence of a possible vancomycin resistant *Staphylococcus aureus* (VRSA). A positive screen test is highly suggestive of a VRSA. The user must confirm the resistance to vancomycin by performing an offline test as recommended by CLSI [M100-S15, vol 25 no. 1, January 2005], or the local authorities and/or regulatory agency.

Principle of the Procedure

The AST card for VITEK® 2 systems is an automated test methodology based on the Minimum Inhibitory Concentration (MIC) technique reported by MacLowry and Marsh (1) and Gerlach (2). The AST card is essentially a miniaturized and abbreviated version of the doubling dilution technique for MICs determined by the microdilution method (3).

Each test card contains 64 microwells. A control well, that contains only microbiological culture medium, is resident on all cards, with the remaining wells containing premeasured amounts of specific antimicrobials combined with culture medium.

The isolate to be tested must be diluted to a standardized concentration in 0.45% saline before being used to rehydrate the card. The card is then filled, sealed, and placed into the instrument incubator/reader. The instrument monitors the growth of each well in the card over a defined period of time (up to 18 hours for bacteria or up to 36 hours for yeast). At the completion of incubation, MICs are determined for each antimicrobial on the card.

Reagents

AST Card Contents

When used with VITEK® 2 instrumentation, the AST card is a complete system for routine susceptibility testing. Each AST card contains selected

antimicrobials in varying concentrations, dried with a microbiological culture medium. For a list of antimicrobials and concentrations contained on specific AST cards, see the respective package inserts.

Precautions

IMPORTANT: For In Vitro Diagnostic Use Only

- Card performance may be compromised if an organism suspension is used that is not within the appropriate range with the DENSICHEK instrument.
- Do not use the card after the expiration date shown on the package liner.
- Store the card unopened in the package liner. Do not use the card if the protective package liner has been damaged, or if no desiccant is present.
- Allow the card to come to room temperature before opening.
- Do not use powdered gloves. Powder may interfere with the optics.
- Ensure that cards are filled properly and do not load any cards that are filled improperly. Prior to inoculation, inspect cards for tape tears or damage to the tape and discard any that are suspect. Check the saline level in the tubes after the vacuum fill.
- Use of a culture medium other than the recommended types must be validated for acceptable performance by the customer laboratory.
- The card performs as intended only when used in conjunction with VITEK® 2 systems.
- Use clear plastic (polystyrene) test tubes only. Do not use glass test tubes. Variation exists among test tubes of standard diameter. Carefully place the tube into the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
- Give special consideration to specimen source and patient drug or antimicrobic regimen. There are antimicrobials included in AST cards that are not proven to be effective for treating infections for all organisms that may be tested. For interpreting and reporting results of antimicrobials shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antibiotic labeling or the most recent CLSI M100 Performance Standard, Table 1: "Suggested groupings of U.S. FDA approved antimicrobial agents that should be considered for routine testing and

reporting by clinical laboratories" and Table 2: "MIC Interpretive Standards."

- Interpretation of test results requires the judgment and skill of a person knowledgeable in antimicrobial susceptibility testing. Additional testing may be required (4).

WARNING

All patient specimens and microbial cultures are potentially infectious and should be treated with universal precautions (9, 10).

Storage and Handling

Upon receipt, store VITEK® 2 AST cards unopened in their original package liner at 2 °C to 8 °C.

Instrument

The VITEK® 2 instruments are a family of *in vitro* diagnostic devices intended to rapidly assess the antimicrobial susceptibility of bacterial pathogens to available antimicrobial agents. For complete information on use and operation of the instrument, see the instrument user manual.

Specimen Preparation

For information on Specimen Preparation, see the following Culture Requirements Table.

Culture Requirements Table

Table 6-1: Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	Inoculum Density	Dilution for AST	Age of Suspension Before Loading Instrument
AST Gram-Negative	TSAB CBA MAC	8 to 24 hours	35 °C to 37 °C Aerobic, non-CO_2	0.50 to 0.63 McFarland Standard	145 µL in 3.0 mL saline	≤ 30 minutes
AST Gram-Positive	TSAB CBA	18 to 24 hours	35 °C to 37 °C 5% to 10% or Aerobic, non CO_2	0.50 to 0.63 McFarland Standard	280 µL in 3.0 mL saline	≤ 30 minutes
AST YEAST	SDA SDA+ Alb ID2 CBA CHBA TSAHB BCP TSA CHOC PVX TSAB CID2 CPS ID3 SAB SAB GLU	18 to 96 hours	35 °C to 37 °C Aerobic, non-CO_2	1.80 to 2.20 Mcfarland Standard	280 µL in 3.0 mL saline	≤ 30 minutes
GN and AST GN pair	CBA[1] MAC[1] TSAB	18 to 24 hours	35 °C to 37 °C Aerobic, non-CO_2	0.50 to 0.63 McFarland Standard	145 µL in 3.0 mL saline	≤ 30 minutes
GP and AST GP pair	TSAB[1] CBA[1]	18 to 24 hours	35 °C to 37 °C 5% to 10% CO_2 or Aerobic, non-CO_2	0.50 to 0.63 Mcfarland Standard	280 µL in 3.0 mL saline	≤ 30 minutes

Table 6-1: Culture Requirements Table

VITEK® 2 Card	Media	Age of Culture	Incubation Conditions	Inoculum Density	Dilution for AST	Age of Suspension Before Loading Instrument
YST and AST YEAST Pair	SDA[1] TSAB[1] CBA TSA CHBA CPS-ID3	18 to 72 hours	35 °C to 37 °C aerobic, non-CO_2	1.80 to 2.20 McFarland Standard	280 µL in 3.0 mL saline	≤ 30 minutes

[1]These media were used in the identification product database developments and will give optimal performance.

Culture Requirements Table — Media Abbreviations

Alb ID2 = Albicans ID2 Agar

BCP = Bromocresol Purple Agar

CBA = Columbia sheep blood agar

CHBA = Columbia Horse Blood Agar

CHOC PVX = Chocolate Agar w/ Polyvitex

CID2 = Candida ID2 Agar

CPS ID3 = CPS ID3 Agar

MAC = MacConkey agar

SAB = Sabouraud Agar

SAB GLU = Sabouraud Agar w/ 2% glucose

SDA = Sabouraud Dextrose Agar

SDA+ = Sabouraud Dextrose Agar w/Gentamicin and Chloramphenicol

TSA = Trypticase Soy Agar

TSAB = Trypticase soy agar with 5% sheep blood

TSAHB = Trypticase Soy Agar w/ Horse Blood

Procedure

Materials

When used with VITEK® 2 instrumentation, the AST card is a complete system for routine susceptibility testing.

Materials required are:

- VITEK® 2 AST Card
- VITEK 2 DENSICHEK™
- DENSICHEK Power Adapter
- Lithium Battery of DENSICHEK
- DENSICHEK Calibrator
- VITEK® 2 Compact Cassette
- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- 12 x 75 mm clear plastic (polystyrene) disposable test tubes
- Sterile sticks or swabs
- Appropriate agar medium (See Culture Requirements Table on page 6-6.)
- Micropipettes–to deliver 145 µL and 280 µL.
- Disposable pipette tips

Optional accessories:

- Saline dispenser
- Predispensed saline test tubes (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- Test tube caps
- Vortex

Test Card Setup Procedure

The following procedure contains general information applicable to all susceptibility products. See the Culture Requirements Table on page 6-6 for product-specific information.

1) Select **isolated colonies** from a primary plate if culture requirements are met,
or
Subculture organism to be tested to an appropriate agar medium and incubate accordingly.

Note: *Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required. A purity check plate is recommended to ensure that a pure culture was used for testing.*

2) Aseptically transfer 3.0 mL of sterile saline (0.45% to 0.5% NaCl, pH 4.5 to 7.0) into a clear plastic (polystyrene) test tube (12 x 75 mm).

3) Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2. Prepare the homogenous organism suspension with a density equivalent to the appropriate McFarland No. (see the Culture Requirements Table on page 6-6) using a calibrated DENSICHEK.

4) In a second tube containing 3.0 mL of saline, transfer 145 µL of the adjusted suspension prepared in step 3 for AST-GN cards, or 280 µL of the adjusted suspension for AST-GP or AST-YS cards.

Note: *Age of suspension must not exceed 30 minutes before inoculating card.*

5) Place the dilution tube prepared in step 4 and AST card in the cassette.

6) Refer to the user manual for instructions on data entry and how to load the cassette into the instrument.

7) Follow the local inspecting agency's guidelines for disposal of hazardous waste.

Quality Control

QC organisms and their expected results can be found in the package insert and should be processed according to the procedure for patient isolates outlined in this document.

Frequency of QC Testing (as defined by CLSI)

Refer to the "CLSI Reference Guide document number M7-A6."

Testing and Storage of QC Organisms

All organisms except yeast:

- Rehydrate the organism according to the manufacturer's instructions.
- Subculture to Trypticase Soy Agar with 5% sheep blood (TSAB).
- Incubate at 35 °C for 24 hours.
- Gram-positive organisms may require a 3% to 5% CO_2 atmosphere.
- Check for purity.
- Subculture to a TSAB plate.
- Incubate 16 to 18 hours at 35 °C.

Yeast:

- Rehydrate the organism according to the manufacturer's instructions.
- Subculture to Sabouraud Agar (SAB) or Sabouraud Dextrose Agar (SDA).
- Incubate at 35 °C for 24 hours.
- Check for purity.
- Subculture to a SAB or SDA plate.
- Incubate at 35 °C for 24 hours (Candida species) or 48 hours (*Crytococcus neoformans*).

Storage Conditions for QC Organisms:

Short-Term Storage

1) Streak to a TSAB plate or slant (SAB or SDA for yeast).

2) Incubate for 24 hours.

3) Refrigerate at 2 °C to 8 °C for up to two weeks.

4) Subculture once as described above and use for QC.

Long-Term Storage

1) Make a heavy suspension in Trypticase Soy Broth (TSB) with 15% glycerol.

2) Freeze at -70 °C.

3) Subculture twice to TSAB before running QC (SAB or SDA for yeast).

Note: *Avoid repeated thawing and refreezing by either freezing in single-use aliquots or removing a small portion of frozen organism preparation with a sterile applicator stick.*

Results

Susceptibility Analytical Techniques

The system evaluates each organism growth pattern in the presence of the antimicrobial in relation to the growth in the control well. Several parameters based on the growth characteristics observed are used to provide appropriate input for the MIC calculations. Discriminant analysis is used to develop the algorithm that determines the susceptibility result for all antimicrobials or antifungals on VITEK® 2 systems. The MIC result must be linked to an organism identification in order to determine a category interpretation. Accurate identification is critical, especially with certain organism/antibiotic combinations (e.g., *Staphylococcus aureus* / oxacillin). In cases where the identification of an organism is in question, confirmatory testing is necessary in order to assure correct interpretation of susceptibility results. A category interpretation will be reported along with an MIC, according to the interpretations defined by CLSI or Comité de l'Antibiogramme de la Société Française de Microbiologie (CA-SFM), or to an adaptation of the global settings according to other local guidelines.

Combination Antibiotics

The MICs for the combination antimicrobials are listed on the laboratory and patient reports as the first concentration. (Example: ampicillin/sulbactam ≤ 8/4 µg/mL is reported as ≤ 8 µg/mL.) The actual concentrations for each value in the antimicrobial calling range are as follows:

- amoxicillin/clavulanic acid (µg/mL) 2/1, 4/2, 8/4, 16/8, 32/16
- ampicillin/sulbactam (µg/mL) 2/1, 4/2, 8/4, 16/8, 32/16
- piperacillin/tazobactam (µg/mL) 4/4, 8/4, 16/4, 32/4, 64/4, 128/4
- ticarcillin/clavulanic acid (µg/mL) 8/2, 16/2, 32/2, 64/2, 128/2
- trimethoprim/Sulfamethoxazole: **Note exception** - This drug is listed on the laboratory and patient reports as the sum of the two antibiotic concentrations: 20 µg/mL = 1/19, 40 µg/mL = 2/38, 80 µg/mL = 4/76, 160 µg/mL = 8/152, 320 µg/mL = 16/304.

Antibiotic Deduction

Deduced antibiotics only report an interpretive result and are noted with a "+." For specific information regarding equivalent and/or phenotypic deductions, refer to the online user manual.

Suppression of Results

A result for an organism/antimicrobial combination which may have a limitation listed in the package insert (e.g., performance issues) may be suppressed from reporting. Refer to the online user manual for a description and instructions about suppression of results.

Clinical Efficacy

There are antimicrobials included on AST cards that are not proven to be effective for treating infections for all organisms that may be tested. For interpreting and reporting of antimicrobial results which have shown to be active against organism groups both *in vitro* and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling or the local therapy guidelines.

Urinary Use Only Antimicrobials

Certain antimicrobial agents are limited to use in treating urinary tract infections. According to CLSI, the following agents should not be reported against pathogens recovered from infection sites other than the urinary tract (except where noted):

- Nalidixic Acid
- Nitrofurantoin
- Norfloxacin
- Trimethoprim/sulfamethoxazole (may also be appropriate for reporting on non-urinary tract isolates)

Limitations

The VITEK® 2 AST card cannot be used with direct clinical samples or other sources containing mixed flora. Any change or modification in the procedure may affect the results. For organism/antimicrobial specific limitations, see the package insert.

Expected Values

Expected results for susceptibility tests will vary based on location and institution. The VITEK® 2 systems were tested at several geographically

diverse locations to assure that trends that occur by location were integrated into the performance characteristics of the system. Organism resistance patterns will differ by institution; therefore, expected values will be directly related to the population of organisms at each site.

Performance Characteristics

The performance characteristics of the antimicrobial agents included in VITEK® 2 AST cards were established at multiple clinical laboratories. The VITEK® 2 AST card results were compared to results from a reference method prepared according to the CLSI approved procedure. Essential agreement (EA) represents VITEK® 2 results that agree exactly with or are within ±1 twofold dilution of the reference result (±2 twofold dilutions for antifungals).

Category agreement (CA) occurs when the VITEK® 2 and the CLSI reference interpretative result agree (Susceptible, Intermediate, and Resistant). There are instances when the category agreement for an antimicrobial falls below the essential agreement. This can occur when a significant number of MICs cluster around a category breakpoint during clinical trial testing, resulting in interpretative errors (for a description of interpretative errors, see the footnote below the tables entitled VITEK® 2 Antimicrobial Specific Performance Characteristics). When the majority of the errors are of the minor type, a high corresponding essential agreement percentage will demonstrate that the antimicrobial retains an acceptable overall performance.

For US Customers only. There are instances when the interpretation is based solely on category agreement (CA) because at the time the performance was established less than five discrete two-fold dilutions were evaluated. A minimum of five dilutions is necessary to perform essential agreement (EA) based on ± one two-fold dilution. These instances are designated by a "c" footnote in individual product package inserts. The following performance table has values for CA only when EA was not established at the time of FDA clearance.

Reproducibility of VITEK® 2 systems was established using a set of on-scale organisms.

Table 6-2: VITEK® 2 Antimicrobial Specific Performance Characteristics for Gram Negative AST

Performance Characteristics for Gram Negative AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Amikacin	AN	CLSI	#, E	98.0	0.0	0.4	0.0	96.5	0.0	0.4	2.9	100
		CA-SFM	I	96.1	4.2	0.6	1.4	-	-	-	-	
Amoxicillin/ Clavulanic Acid	AMC	CLSI	#, E	96.3	0.8	0.0	2.4	92.1	0.8	0.0	6.5	100
Ampicillin	AM	CLSI	#, E	93.3	1.3	0.0	0.8	90.9	1.3	0.0	7.8	99.3
		CA-SFM	I	94.9	0.6	2.2	4.3	-	-	-	-	
Ampicillin/ Sulbactam	SAM	CLSI	#, E	96.9	0.0	0.6	0.6	88.7	0.0	0.6	11.0	99.6
		CA-SFM	I	94.2	0.9	0.5	5.1	84.3	0.9	0.5	15.1	
Aztreonam	ATM	CLSI	#, E	98.9	1.6	0.3	0.3	96.6	1.6	0.3	0.3	100
		CA-SFM	I	93.7	0.8	0.2	5.2	-	-	-	-	
Cefalotin (Cephalothin)	CF	CLSI	#, E	97.3	0.8	0.0	1.2	89.4	0.8	0.0	10.6	96.7
		CA-SFM	I	95.7	0.2	0.4	3.3	-	-	-	-	
Cefazolin	CZ	CLSI	#, E	96.8	1.2	3.0	2.8	95.8	1.2	3.0	4.1	97.4
Cefepime	FEP	CLSI	#, E	94.2	4.0	1.4	6.3	92.1	-	-	-	98.6
Cefixime	CFM	CLSI	I	96.3	0.3	1.5	1.1	92.3	0.4	1.5	6.8	99.8
		CA-SFM	I	96.3	0.3	1.5	1.1	92.3	0.4	1.5	6.8	

Table 6-2: VITEK® 2 Antimicrobial Specific Performance Characteristics for Gram Negative AST

Performance Characteristics for Gram Negative AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Cefoperazone	CFP	CLSI	I	94.8	1.8	1.5	2.3	87.4	1.8	1.5	11.2	99.2
		CA-SFM	I	94.8	0	0.6	3.4	87.2	0	0.6	12.5	
Cefotaxime	CTX	CLSI	#, E	95.8	1.1	0.2	2.6	92.9	1.1	0.2	6.7	98.1
		CA-SFM	I	94.0	0.4	0.1	3.5	-	-	-	-	
Cefotetan	CTT	CLSI	#, E	97.9	1.0	0.0	0.9	97.5	1.0	0.0	2.3	98.5
		CA-SFM	I	95.8	0.6	0.0	3.5	-	-	-	-	
Cefoxitin	FOX	CLSI	#, E	97.2	0.9	0.0	1.5	92.2	0.9	0.0	8.7	98.9
		CA-SFM	I	95.1	0.5	0.2	3.4	-	-	-	-	
Cefozopran	CZO	Global	E	98.1	4.8	0.5	0.6	98.0	4.8	0.5	1.4	100
Cefpirome	CPO	CA-SFM	I	94.8	0	0.2	1.9	94.5	0	0.2	5.3	99
Cefpodoxime	CPD	CLSI	#, E	96.0	0.0	0.4	0.8	96.3	0.0	0.4	3.5	100
		CA-SFM	I	94.1	1.2	2.9	1.3	-	-	-	-	
Ceftazidime	CAZ	CLSI	#, E	97.5	1.1	0.2	1.0	97.3	1.1	0.2	3.5	95.4
		CA-SFM	I	92.3	5.1	0.0	4.1	-	-	-	-	
Ceftizoxime	CZX	CLSI	#, E	93.6	2.7	1.9	3.2	90.4	2.7	1.9	9.0	98.2
		CA-SFM	I	95.6	1.0	0.1	3.1	-	-	-	-	

Table 6-2: VITEK® 2 Antimicrobial Specific Performance Characteristics for Gram Negative AST

Performance Characteristics for Gram Negative AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Ceftriaxone	CRO	CLSI	#, E	95.8	1.1	0.5	3.0	90.2	1.1	0.5	9.3	98.5
		CA-SFM	I	93.0	0.4	0.6	4.2	-	-	-	-	
Cefuroxime	CXM	CLSI	#, E	95.3	1.5	1.0	1.6	93.9	1.5	1.0	4.8	99.6
Chloramphenicol	C	CLSI	I	95.3	0.8	0	3.0	86.2	0.8	0	13.4	96.1
		CA-SFM	I	95.3	0.8	0	3.0	86.2	0.8	0	13.4	
Ciprofloxacin	CIP	CLSI	#, E	97.9	0.0	0.0	0.5	96.6	0.0	0.0	3.8	98.9
		CA-SFM	E	97.9	0.0	0.0	0.5	96.6	0.0	0.0	3.8	
Colistin	CS	CA-SFM	I	96.1	3.4	0.7	0	97.3	5.4	1.4	N/A	99.2
Ertapenem	ETP	CLSI	#, E	-	-	-	-	98.8	0	0	1.2	97.8
Extended-Spectrum Beta-Lactamase (ESBL)	ESBL	CLSI	#, E	-	-	-	-	97.7	2.2	1.9	N/A	100
Flomoxef	FLO	Global	E	97.0	0.0	0.0	1.8	97.5	0.0	0.0	2.5	100
Fosfomycin	FOS	CLSI	E	92.0	14.9	3.6	-	90.1	24.8	5.4	-	99.6
Gatifloxacin	GAT	CLSI	#, E	99.7	0.0	0.0	0.0	97.5	0.0	0.0	2.5	100
Gentamicin	GM	CLSI	#, E	97.1	1.9	0.0	0.6	96.4	1.9	0.0	2.9	100
		CA-SFM	E	97.1	1.9	0.0	0.6	96.4	1.9	0.0	2.9	

Table 6-2: VITEK® 2 Antimicrobial Specific Performance Characteristics for Gram Negative AST

Performance Characteristics for Gram Negative AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Imipenem	IPM	CLSI	#, E	93.6	3.0	0.2	1.9	95.8	3.0	0.2	3.2	95.2
		CA-SFM	E	93.6	3.0	0.2	1.9	95.8	3.0	0.2	3.2	
Isepamicin	ISP	CA-SFM	I	94.6	0	0.2	1.7	95.2	0	0.2	4.6	99.6
Levofloxacin	LEV	CLSI	#, E	98.4	0.0	0.0	0.2	97.7	0.0	0.0	2.3	100
Mecillinam	MEC	Global	E	93.0	-	-	-	88.5	12.0	0.0	10.6	97
Meropenem	MEM	CLSI	#, E	98.3	0.0	0.0	0.4	98.3	0.0	0.0	1.7	96
		CA-SFM	E, E. Coli	98.3	0.0	0.0	0.4	98.3	0.0	0.0	1.7	
Mezlocillin	MZ	CLSI	I, P. aerug.	97.4	1.2	2.9	0	88.3	2.4	22.9	0	98.8
		CLSI	I, Others	92.6	0.6	0.6	5.3	86	1.2	2.8	12.1	
		CA-SFM	I, All	92.6	0.9	1.1	5.5	86.6	0.9	1.1	12.6	
Minocycline	MNO	CLSI	I	94.7	0.3	1.3	2.3	84.8	0.3	1.3	14.3	98
		CA-SFM	I	94.7	0.3	1.3	2.3	84.8	0.3	1.3	14.3	
Moxifloxacin	MXF	CLSI	#, E	98.7	0.0	0.0	0.0	97.8	2.2	0.0	0.0	100
Nalidixic Acid	NA	CLSI	#, E	98.4	0.0	0.0	N/A	98.9	0.9	0.9	N/A	100
Netilmicin	NET	CLSI	I	95.4	1.1	0.6	1.5	-	-	-	-	99.6
		CA-SFM	I	95.4	0.9	1.0	1.2	-	-	-	-	

Table 6-2: VITEK® 2 Antimicrobial Specific Performance Characteristics for Gram Negative AST

Performance Characteristics for Gram Negative AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Nitrofurantoin	FT	CLSI	#, E	93.6	0.0	0.0	4.3	78.8	0.0	0.0	17.9	100
		CA-SFM	I	94.8	0.2	0.4	4.0	-	-	-	-	
Norfloxacin	NOR	CLSI	#, E	97.4	3.1	0.0	1.3	95.7	3.1	0.0	3.8	100
		CA-SFM	I	95.1	1.5	0.3	3.5	-	-	-	-	
Ofloxacin	OFL	CLSI	I	96.9	2.1	0.3	0.7	93.6	2.1	0.3	5.8	100
		CA-SFM	I	96.7	0.9	0	2.6	91.1	0.9	0	8.8	
Panipenem	PAN	Global	E	95.8	2.7	0.5	0.9	90.5	2.7	0.5	8.9	100
Pefloxacin	PEF	CA-SFM	I	97.9	0.6	0	1.0	94	0.6	0	5.9	100
Piperacillin	PIP	CLSI	#, E	96.0	0.0	0.0	3.3	91.9	0.0	0.0	9.4	95.6
		CA-SFM	I	93.0	1.0	0.6	5.4	-	-	-	-	
Piperacillin/ Tazobactam	TZP	CLSI	#, E	95.6	1.4	0.0	3.0	94.3	1.4	0.0	6.1	100
		CA-SFM	I	93.9	1.0	0.2	4.6	-	-	-	-	
Rifampicin (Rifampin)	RA	CA-SFM	E, Acineto.	96.6	0.0	0.0	3.4	80.0	0.0	0.0	20.0	100
Temocillin	TEM	Global	E	96.9	2.9	1.3	-	97.3	4.4	2.1	-	100
Tetracycline	TE	CLSI	#, E	95.5	1.0	0.0	1.4	93.0	1.0	0.0	6.6	100

Table 6-2: VITEK® 2 Antimicrobial Specific Performance Characteristics for Gram Negative AST

Performance Characteristics for Gram Negative AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Ticarcillin	TIC	CLSI	#, E	97.2	0.0	0.5	1.4	91.7	0.4	2.6	7.5	97.8
		CA-SFM	I	92.6	1.4	0.2	4.5	-	-	-	-	
Tigecycline	TGC	Global	E	94.4	0	2.0	0	90.1	0	2.0	8.5	100
Ticarcillin/ Clavulanic Acid	TCC	CLSI	#, E	98.9	0.0	1.9	0.6	92.7	0.0	1.9	19.6	100
		CA-SFM	I	94.8	2.2	0.3	4.1	-	-	-	-	
Tobramycin	TM	CLSI	#, E	98.0	0.0	0.0	1.2	94.7	0.0	0.0	5.6	100
		CA-SFM	E	98.0	0.0	0.0	1.2	94.7	0.0	0.0	5.6	
Trimethoprim	TMP	CLSI	I	93.7	1.6	1.0	N/A	96.4	3.0	4.0	0	100
		CA-SFM	I	93.7	1.0	1.1	1.2	93.4	1.0	1.1	5.7	
Trimethoprim/ Sulfamethoxazole	SXT	CLSI	#, E	99.5	1.0	0.0	N/A	98.4	1.0	1.7	N/A	100
		CA-SFM	I	96.0	0.7	0.7	1.9	—	—	—	—	

[1]Abbreviations: Bkpt = breakpoint committee; CLSI = Clinical and Laboratory Standards Institute; CA-SFM = Comité de l'Antibiogramme de la Société Française de Microbiologie; EA = essential agreement; CA = category agreement; VME = very major error (susceptible result with resistant reference result); ME = major error (resistant result with susceptible reference result); mE = minor error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result); Repro = reproducibility.

[2]Comment - specific organism groups are designated as *P. aerug.* for *Pseudomonas aeruginosa,* others for species other than *Pseudomonas aeruginosa,* and Acineto. for Acinetobacter.

Key

# = US Food and Drug Administration 510(k) cleared
E = External performance data
I = Internal performance data
– = Not available
N/A = Not applicable

Table 6-3: VITEK® 2 Antimicrobial Specific Performance Characteristics for Gram Positive AST

Performance Characteristics for Gram Positive AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Amikacin	AN	CLSI	I, *Staph*	98.8	0	0	0.2	96.1	0	0	3.9	100
		CA-SFM	I, *Staph*	98.8	6.7	0	0.5	95.4	0.3	0	4.3	
Ampicillin	AM	CLSI	#, E	97.6	1.1	0.3	0.2	99.5	2.2	0.6	0.2	97
Ampicillin/ Sulbactam	SAM	CLSI	#, E	–	–	–	–	96.9	–	–	–	99.6
Benzylpenicillin (Penicillin)	P	CLSI	#, E	97.4	0.4	0.3	N/A	98.5	0.9	1.0	N/A	99.3
Cefazolin	CZ	CLSI	#, E	–	–	–	–	97.1	–	–	–	98.1
Cefmetazole	CMZ	CLSI	E, *Staph*	–	–	–	–	100%	0	0	0	100
Cefotaxime	CTX	CLSI	E, S.aga	100	0	0	N/A	100	0	0	N/A	99.6
Cefoxitin	OXSF	CLSI	E, Ref. = CLSI Disk Diffusion	–	–	–	–	98.3	2	1.4	N/A	100
Cefoxitin			E, Ref. = *mec*A PCR	–	–	–	–	97.2	2.3	3.2	N/A	
Oxacillin + Cefoxitin Screen		CLSI	#, Ref. = CLSI cefoxitin Disk Diffusion	–	–	–	–	98.5	0.4	2.8	N/A	–

Table 6-3: VITEK® 2 Antimicrobial Specific Performance Characteristics for Gram Positive AST

Performance Characteristics for Gram Positive AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Oxacillin + Cefoxitin Screen		CLSI	E, Ref. = *mec*A PCR	–	–	–	–	97.8	1.2	3.2	N/A	–
Cefuroxime	CXM	CLSI	E	–	–	–	–	99.7	0	0	0.3	100
		CA-SFM	E	–	–	–	–	99.5	0.3	0	0.3	
Chloramphenicol	C	CLSI	#, E	99.7	3.1	0.1	0.3	97.8	3.1	0.1	2.7	100
		CA-SFM	E	99.7	3.1	0.1	0.3	97.8	3.1	0.1	2.7	
Ciprofloxacin	CIP	CLSI	#, E	99.3	1.4	0	0.2	96.7	1.4	0	2.9	100
		CA-SFM	E	99.3	1.4	0	0.2	96.7	1.4	0	2.9	
Clindamycin	CM	CLSI	#, E	98.7	2.3	0	0.7	99.1	2.3	0	0.9	98.5
		CA-SFM	I	96.1	2.5	4.3	0	–	–	–	–	
Daptomycin	DAP	CLSI	#	98.2	0	0	0	100	0	0	0	100
Ertapenem	ETP	CLSI	#	–	–	–	–	99.8	0.4	0	0	100
Erythromycin	E	CLSI	#, E	95.9	0.4	0.4	5.1	92.8	0.4	0.4	7.5	95.2
		CA-SFM	I	98.5	1.2	0	0.5	–	–	–	–	
Fosfomycin	FOS	CA-SFM	I, *Staph*	97.1	6.5	0.3	N/A	95.8	11.8	1.7	N/A	100
Fusidic Acid	FA	CA-SFM	I, *Staph*	100	0	0	0	99.2	0	0	0.8	100
Gatifloxacin	GAT	CLSI	#, E	99.5	0	0.4	0.3	80.5	0	0.2	19.2	100

Table 6-3: VITEK® 2 Antimicrobial Specific Performance Characteristics for Gram Positive AST

Performance Characteristics for Gram Positive AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Gentamicin	GM	CLSI	#, E, *Staph*	99.2	0	0	0.8	95.1	0	0	4.9	100
		CA-SFM	E, *Staph*	99.2	0	0	0.8	95.1	0	0	4.9	
Gentamicin High Level	HLG	CLSI	#, E	N/A	N/A	N/A	N/A	100	N/A	N/A	N/A	100
		CA-SFM	E, *Enc*	N/A	N/A	N/A	N/A	100	N/A	N/A	N/A	
Habekacin	HAB	Global	E, *Staph*	100	0	0	0	100	0	0	0	100
Imipenem	IPM	CLSI	E	–	–	–	–	99.2	0.4	0.5	0.3	100
		CA-SFM	E	–	–	–	–	99.2	0.4	0.5	0.3	
Kanamycin	K	CLSI	E, *Staph*	99.2	0.8	0.3	0	97.3	0.8	0.4	2.2	100
		CA-SFM	E, *Staph*	99.2	0	0.3	0.5	98.9	0	0.4	0.8	
Kanamycin High Level	HLK	CA-SFM	I, *Enc*	N/A	N/A	N/A	N/A	100	N/A	N/A	N/A	99.3
Levofloxacin	LEV	CLSI	#, E	99.3	0	0	0.2	95.8	0	0	4.2	100
Lincomycin	L	CA-SFM	E, *Staph*	99.5	1.0	0	0.3	99.2	1.0	0	0.5	96.7
Linezolid	LNZ	CLSI	#, E	98.7	0	0.1	0.1	98.9	0	0.1	1.0	100
		CA-SFM	E	98.7	0	0.1	0.7	92.6	0	0.1	7.3	
Minocycline	MNO	CLSI	#, E	96.6	0	1.5	0.2	91.4	0	1.5	7.5	100
		CA-SFM	E	96.6	0	1.5	0.2	91.4	0	1.5	7.5	

Table 6-3: VITEK® 2 Antimicrobial Specific Performance Characteristics for Gram Positive AST

Performance Characteristics for Gram Positive AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Moxifloxacin	MXF	CLSI	#, E	99.2	0	0	0	83.3	0	0	16.7	100
		CA-SFM	E	98.5	0	0	0.1	92.4	0	0	7.6	
Mupirocin	MUP	CA-SFM	E	99.7	0	0	0	100	0	0	0	100
		Global	E	99.7	0	0.3	0	99.2	0	0.9	0	
Netilmicin	NET	CLSI	I, *Staph*	96.9	0	0	1.2	98.6	0	0	1.4	100
		CA-SFM	I, *Staph*	96.9	50.0	1.0	0.2	93.0	50.0	1.0	5.8	
Nitrofurantoin	FT	CLSI	#, E	98.3	0	1.4	0	91.7	0	1.4	7	100
Norfloxacin	NOR	CLSI	#, E	99.2	0	0	0	94.1	0	0	5.9	100
		CA-SFM	I	97.5	1.4	0	0.8	–	–	–	–	
Ofloxacin	OFL	CLSI	#, E	99	1.4	0	0.2	97.3	1.4	0	2.1	100
		CA-SFM	I	99.6	0	0	0.4	–	–	–	–	
Oxacillin MIC	OX	CLSI	#, E, *Staph*	97.4	1.6	1.1	0	97.1	2.2	3.4	0	98.1
Pefloxacin	PEF	CA-SFM	I, *Staph*	99.1	2.1	0	0.3	98.1	0	0	1.9	100
Pristinamycin	PT	CA-SFM	I, *Staph*	99.2	0	0.3	0	85.5	0	0.4	14.2	100
Quinupristin/ dalfopristin	QDA	CLSI	#, E	96.6	1.2	0	0.2	94.8	1.2	0	4.9	100
		CA-SFM	E	96.1	0	0	2.3	86.5	0	0	13.5	

Table 6-3: VITEK® 2 Antimicrobial Specific Performance Characteristics for Gram Positive AST

Performance Characteristics for Gram Positive AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Rifampicin (Rifampin)	RA	CLSI	#, E, *Staph*	100	0	0	0	100	0	0	0	99.6
		CA-SFM	I, *Staph*	99.5	0	0	0.3	–	–	–	–	
Sparfloxacin	SPX	CLSI	#, E	98.8	0	0	0	100	0	0	0	98
		CA-SFM	I	95.7	2.0	0	0.6	–	–	–	–	
Streptomycin High Level	HLS	CLSI	#, E, *Enc*	N/A	N/A	N/A	N/A	100	N/A	N/A	N/A	100
		CA-SFM	E, *Enc*	–	–	–	–	100	0	0	–	
Teicoplanin	TEC	CLSI	I	96.6	3.3	0.3	0.4	95.7	3.3	0.3	2.7	99.4
		CA-SFM	I	96.9	1.6	0	1.1	95.9	1.6	0.3	3.2	
Tetracycline	TE	CLSI	#, E	99.1	1.2	0.4	0.5	99.3	1.2	0.5	0.8	94.8
Tobramycin	TM	CLSI	E, *Staph*	99.5	0	0	0.3	95.1	0	0	4.9	100
		CA-SFM	E, *Staph*	99.5	0	0	0.3	95.1	0	0	4.9	
Trimethoprim	TMP	CLSI	E	98.9	0	0	N/A	99.5	0	0.7	N/A	100
		CA-SFM	E	98.2	0.8	0.4	0.6	95.5	0.8	0.8	3.7	

Table 6-3: VITEK® 2 Antimicrobial Specific Performance Characteristics for Gram Positive AST

Performance Characteristics for Gram Positive AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Trimethoprim/ Sulfamethoxazole	SXT	CLSI	#, E, S. aureus, SXT1	–	–	–	–	99.6	0	0.5	N/A	99.6
		CLSI	E, Staph, SXT1	99.2	3.2	0.3	N/A	98.7	4.8	0.5	N/A	
		CA-SFM	E, Staph, SXT1	99.0	0	0	1.0	96.7	0	0	3.3	
Trimethoprim/ Sulfamethoxazole	SXT	CLSI	I, SXT2	97.3	1.6	1.5	0	–	–	–	–	97.6
		CA-SFM	I, SXT2	97.3	0	0.8	1.8	–	–	–	–	
Vancomycin	VA	CLSI	#, E	99	0	0.1	0.9	97.9	0	0.1	4.0	100
		CA-SFM	E	99	0	0.1	0.9	97.9	0	0.1	4.0	

[1]Abbreviations: Bkpt = breakpoint committee; CLSI = Clinical and Laboratory Standards Institute; CA-SFM = Comité de l'Antibiogramme de la Société Française de Microbiologie; EA = essential agreement; CA = category agreement; VME = very major error (susceptible result with resistant reference result); ME = major error (resistant result with susceptible reference result); mE = minor error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result); Repro = reproducibility.

[2]Comment - specific organism groups are designated as *Staph* for *staphylococci*, *Enc* for *enterococci*, and S. aga for Group B streptococci.

Key # = US Food and Drug Administration 510(k) cleared
E = External performance data
I = Internal performance data

– = Not available
N/A = Not applicable
SXT1 or SXT2 = Comment code which identifies specific performance characteristics.
Appropriate code is referenced in package insert.
REF = Reference method for clinical performance study.

Table 6-4: VITEK® 2 Antimicrobial Specific Performance Characteristics for *Streptococcus pneumoniae* AST

Performance Characteristics for *Streptococcus pneumoniae* AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Amoxicillin	AMX	CLSI	I	99.6	0.0	0.0	0.0	96.0	0.0	0.0	4.0	100
		CA-SFM	I	99.6	0.0	0.0	0.0	95.1	0.0	0.0	4.9	
Benzylpenicillin (Penicillin)	P	CLSI	#, E	97.4	0.0	0.0	1.7	90.5	0.0	0.0	9.4	99.7
		CA-SFM	E	97.4	0.0	0.0	1.7	90.5	0.0	0.0	9.4	
Cefotaxime	CTX	CLSI	#, E	98.2	1.6	0.3	0.9	86.6	1.6	0.3	13.0	99.7
Ceftriaxone	CRO	CLSI	#, E	98.0	0.0	0.0	0.4	90.8	0.0	0.0	9.2	100
Chloramphenicol	C	CLSI	#, E	99.8	2.8	0.0	N/A	98.9	8.6	0.0	N/A	99.3
Ertapenem	ETP	CLSI	#, E	–	–	–	–	94.9	0	0.3	4.9	100
Erythromycin	E	CLSI	#, E	98.7	0.9	0.0	1.1	98.7	0.9	0.0	1.1	99.7
		CA-SFM	E	98.7	0.9	0.0	1.1	98.7	0.9	0.0	1.1	
Gatifloxacin	GAT	CLSI	E	99.6	3.1	0.0	0.0	97.3	3.1	0.0	2.3	100
Imipenem	IPM	CA-SFM	I	98.4	0.0	0.5	N/A	–	–	–	–	100
Levofloxacin	LEV	CLSI	#, E	99.8	0.0	0.2	0.0	99.1	0.0	0.2	0.7	100
		CA-SFM	E	99.8	0.0	0.2	0.0	99.1	0.0	0.2	0.7	

Table 6-4: VITEK® 2 Antimicrobial Specific Performance Characteristics for *Streptococcus pneumoniae* AST

Performance Characteristics for *Streptococcus pneumoniae* AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Linezolid	LNZ	CLSI	#, E	–	–	–	–	100.0	0.0	0.0	0.4	100
		CA-SFM	E	–	–	–	–	100.0	0.0	0.0	0.4	
Moxifloxacin	MXF	CLSI	#, E	99.6	0.0	0.0	0.2	95.0	0.0	0.0	5.0	100
		CA-SFM	E	99.6	0.0	0.0	0.2	95.0	0.0	0.0	5.0	
Ofloxacin	OFL	CLSI	#, E	100.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	100
Pristinamycin	PT	CA-SFM	I	100.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	100
Quinupristiin Dalfopristin	QDA	CLSI	I	99.2	0.0	0.0	0.0	99.6	0.0	0.0	0.4	100
		CA-SFM	I	99.2	0.0	0.0	0.8	93.7	0.0	0.0	6.3	
Rifampicin (Rifampin)	RA	CLSI	E	100.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	100
		CA-SFM	E	100.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	
Sparfloxacin	SPX	CLSI	#, E	96.4	0.0	0.0	0.7	98.2	0.0	0.0	1.8	96.7
		CA-SFM	I	98.4	0.0	0.0	0.0	–	–	–	–	
Telithromycin	TEL	CLSI	#	–	–	–	–	99.5%	0	0	0.5	100
Tetracycline	TE	CLSI	#, E	99.4	1.0	0.0	0.0	99.1	1.0	0.0	0.6	99.3
Trimethoprim/ Sulfamethoxazole	SXT	CLSI	#, E	98.0	0.0	0.0	2.0	84.4	0.0	0.0	15.6	100

Table 6-4: VITEK® 2 Antimicrobial Specific Performance Characteristics for *Streptococcus pneumoniae* AST

Performance Characteristics for *Streptococcus pneumoniae* AST												
Antimicrobial (Common Name)	Drug Code	Bkpt[1]	Comment[2]	Essential Agreement				Category Agreement				Repro
					% Error				%Error			
				%EA	VME	ME	mE	%CA	VME	ME	mE	
Vancomycin	VA	CLSI	#, E	100.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	100
		CA-SFM	E	100.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	

[1]Abbreviations: Bkpt = breakpoint committee; CLSI = Clinical and Laboratory Standards Institute; CA-SFM = Comité de l'Antibiogramme de la Société Française de Microbiologie; EA = essential agreement; CA = category agreement; VME = very major error (susceptible result with resistant reference result); ME = major error (resistant result with susceptible reference result); mE = minor error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result); Repro = reproducibility.

[2]Comment - # = US Food and Drug Administration 510(k) cleared, E = External performance data, I = Internal performance data.

Key – = Not available
N/A = Not applicable

Gram-Negative Reporting Based on CLSI — Important Note

Testing and reporting of results for antimicrobial agents with the various non-fastidious organism groups is based on the CLSI M100 Performance Standards, Table 1: "Suggested groupings of U.S. FDA approved antimicrobial agents that should be considered for routine testing and reporting by clinical laboratories." Based on the current CLSI Performance Standards, there are no longer interpretative criteria for the following gram-negative antimicrobial/organism combinations:

Table 6-5: Organisms without Interpretative Criteria for AST-GN Antimicrobials

AST-GN Antimicrobial	Organisms without interpretative criteria
Ampicillin	*P. aeruginosa* and other *non-Enterobacteriaceae*
Amoxicillin/clavulanic acid	*P. aeruginosa* and other *non-Enterobacteriaceae*
Cefalothin	*P. aeruginosa* and other *non-Enterobacteriaceae*
Cefazolin	*P. aeruginosa* and other *non-Enterobacteriaceae*
Cefixime	*P. aeruginosa* and other *non-Enterobacteriaceae*
Cefotetan	*P. aeruginosa* and other *non-Enterobacteriaceae*
Cefoxitin	*P. aeruginosa* and other *non-Enterobacteriaceae*
Cefpodoxime	*P. aeruginosa* and other *non-Enterobacteriaceae*
Cefuroxime	*P. aeruginosa* and other *non-Enterobacteriaceae*
Nalidixic acid	*P. aeruginosa* and other *non-Enterobacteriaceae*
Trimethoprim	*P. aeruginosa* and other *non-Enterobacteriaceae*

Test results for these combinations should be suppressed. Instructions for suppression of results can be found in the online user manual.

List of Claims

Note: *If the organism is not in the VITEK® 2 susceptibility database, results will not be reported. The following message will appear: "NOTE: Organism not valid for susceptibility testing – perform alternate method."*

Gram-Negative Organisms Claimed for AST-GN (keyid)

Achromobacter denitrificans (formerly known as Achromobacter xylosoxidans ssp. *dentrificans)*
Achromobacter xylosoxidans (formerly known as Achromobacter xylosoxidans ssp. *xylosoxidans)*
Acinetobacter baumannii
Acinetobacter calcoaceticus
Acinetobacter genospecies 3

Acinetobacter haemolyticus
Acinetobacter johnsonii
Acinetobacter junii
Acinetobacter lwoffii
Acinetobacter spp.
Aeromonas caviae
Aeromonas hydrophila
Aeromonas hydrophila/caviae
Aeromonas sobria
Alcaligenes faecalis ssp. *faecalis*
Bordetella avium
Bordetella bronchiseptica
Brevundimonas diminuta
Brevundimonas diminuta/vesicularis
Brevundimonas vesicularis
Burkholderia cepacia
Cedecea davisae
Cedecea lapagei
Cedecea neteri
Chryseobacterium gleum
Chryseobacterium indologenes
Chryseobacterium meningosepticum
Citrobacter amalonaticus
Citrobacter braakii
Citrobacter farmeri
Citrobacter freundii
Citrobacter koseri
Citrobacter youngae
Comamonas testosteroni
Delftia acidovorans
Edwardsiella hoshinae
Edwardsiella tarda
Enterobacter aerogenes
Enterobacter amnigenus
Enterobacter amnigenus 1
Enterobacter amnigenus 2
Enterobacter asburiae
Enterobacter cancerogenus
Enterobacter cloacae
Enterobacter gergoviae
Enterobacter intermedius
Enterobacter sakazakii

Escherichia coli
Escherichia coli ATCC® 25922
Escherichia coli ATCC 35218
Escherichia fergusonii
Escherichia hermannii
Escherichia vulneris
Ewingella americana
Hafnia alvei
Klebsiella oxytoca
Klebsiella pneumoniae
Klebsiella pneumoniae ssp. *ozaenae*
Klebsiella pneumoniae ssp. *pneumoniae*
Klebsiella pneumoniae ssp. *pneumoniae* ATCC 700603
Klebsiella pneumoniae ssp. *rhinoscleromatis*
Klebsiella spp.
Kluyvera ascorbata
Kluyvera cryocrescens
Leclercia adecarboxylata
Mannheimia haemolytica
Moraxella group
Moraxella lacunata
Moraxella nonliquefaciens
Moraxella osloensis
Morganella morganii
Morganella morganii ssp. *morganii*
Morganella morganii ssp. *sibonii*
Myroides spp.
Pantoea agglomerans
Pantoea dispersa
Pasteurella aerogenes
Pasteurella multocida
Pasteurella pneumotropica
Plesiomonas shigelloides
Proteus mirabilis
Proteus penneri
Proteus vulgaris group
Proteus vulgaris group/*Proteus penneri*
Providencia alcalifaciens
Providencia rettgeri
Providencia rustigianii
Providencia stuartii
Pseudomonas aeruginosa

Pseudomonas aeruginosa ATCC 27853
Pseudomonas alcaligenes
Pseudomonas fluorescens
Pseudomonas luteola
Pseudomonas mendocina
Pseudomonas oryzihabitans
Pseudomonas pseudoalcaligenes
Pseudomonas putida
Pseudomonas spp.
Pseudomonas stutzeri
Psychrobacter phenylpyruvicus
Ralstonia pickettii
Raoultella ornithinolytica
Raoultella planticola
Raoultella terrigena
Salmonella enterica ssp. *arizonae (formerly known as Salmonella choleraesuis* ssp. *arizoniae)*
Salmonella enterica ssp. *enterica (formerly known as Salmonella choleraesuis* ssp. *choleraesuis)*
Salmonella ser. *Enteritidis*
Salmonella group
Salmonella ser. Paratyphi A
Salmonella ser. Paratyphi B
Salmonella ser. Paratyphi C
Salmonella spp.
Salmonella ser. *Typhi*
Salmonella ser. *Typhimurium*
Serratia ficaria
Serratia fonticola
Serratia grimesii
Serratia liquefaciens
Serratia liquefaciens group
Serratia marcescens
Serratia odorifera
Serratia plymuthica
Serratia proteamaculans
Serratia rubidaea
Shewanella putrefaciens
Shewanella putrefaciens group
Shigella boydii
Shigella dysenteriae
Shigella flexneri

Shigella group
Shigella sonnei
Shigella spp.
Sphingobacterium multivorum
Sphingobacterium spiritivorum
Sphingomonas paucimobilis
Stenotrophomonas maltophilia
Vibrio alginolyticus
Vibrio fluvialis
Vibrio harveyi
Vibrio metschnikovii
Vibrio mimicus
Vibrio parahaemolyticus
Vibrio vulnificus
Yersinia aldovae
Yersinia enterocolitica
Yersinia enterocolitica group
Yersinia frederiksenii
Yersinia intermedia
Yersinia kristensenii
Yersinia pseudotuberculosis
Yersinia ruckeri

Gram-Positive Organisms Claimed for AST-GP (keyid)

Coagulase-negative *Staphylococcus*
Coagulase-positive *Staphylococcus*
Enterococcus avium
Enterococcus casseliflavus
Enterococcus durans
Enterococcus faecalis
Enterococcus faecalis ATCC 29212
Enterococcus faecalis ATCC 51299
Enterococcus faecium
Enterococcus gallinarum
Enterococcus hirae
Enterococcus malodoratus
Enterococcus mundtii
Enterococcus spp.
Escherichia coli ATCC 35218
Staphylococcus aureus
Staphylococcus aureus ATCC 29213
Staphylococcus aureus ATCC BAA-1026

Staphylococcus auricularis
Staphylococcus capitis
Staphylococcus chromogenes
Staphylococcus cohnii
Staphylococcus cohnii ssp. *cohnii*
Staphylococcus cohnii ssp. *urealyticus (formerly Staphylococcus cohnii* ssp. *urealyticum)*
Staphylococcus epidermidis
Staphylococcus haemolyticus
Staphylococcus hominis
Staphylococcus hominis ssp. *hominis*
Staphylococcus hyicus
Staphylococcus intermedius
Staphylococcus kloosii
Staphylococcus lentus
Staphylococcus lugdunensis
Staphylococcus saprophyticus
Staphylococcus schleiferi
Staphylococcus sciuri
Staphylococcus simulans
Staphylococcus warneri
Staphylococcus xylosus
Streptococcus agalactiae
Streptococcus pneumoniae
Streptococcus pneumoniae ATCC 49619

Yeast Organisms Claimed for AST-YS (Keyid)

Candida albicans
Candida dubliniensis
Candida glabrata
Candida guilliermondii
Candida haemulonii
Candida inconspicua
Candida intermedia
Candida kefyr
Candida krusei
Candida krusei ATCC 6258
Candida lipolytica
Candida lusitaniae
Candida norvegenis
Candida parapsilosis
Candida parapsilosis ATCC 22019

Candida pelliculosa
Candida rugosa
Candida tropicalis
Candida utilis
Cryptococcus neoformans
Stephanoascus ciferrii

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Permission to incorporate portions of M100-S15 (Performance Standards for Antimicrobial Susceptibility Testing: Fifteenth Informational Supplement) in the bioMérieux clinical microbiology instrumentation and System has been granted by CLSI. The current standard and supplements to it may be obtained from CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

bioMérieux, Inc.
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bioMérieux, Inc.
Box 15969,
Durham, North Carolina 27704-0969 USA
tel. (1) 800.682.2666

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bioMérieux sa
au capital de 11 879 045 Euros
673 620 399 RCS LYON
69280 Marcy-l'Etoile/ France
tel. (33) 04 78 87 20 00
fax (33) 04 78 87 20 90
http://www.biomerieux.com

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